Development and feasibility testing of a novel community-based enhanced care intervention to improve person-centred outcomes for people living with HIV/AIDS in Ghana

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Development and feasibility testing of a novel community-based enhanced care intervention to improve person-centred outcomes for people living with HIV/AIDS in Ghana

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Abstract

Background: Although person-centred care (PCC) has been identified as necessary to achieve the 90-90-90 HIV treatment targets, limited research has considered the meaning and practice of PCC in low- and middle-income settings.

Aim: To develop a community-based enhanced care intervention to improve person-centred outcomes for people living with HIV/AIDS, and to test the feasibility of a cluster randomised controlled trial in terms of participant recruitment and retention, and intervention delivery.

Methods: The Medical Research Councils' (MRC) guidance for developing and evaluating complex interventions was used to conduct a sequential mixed methods design. This comprised an initial systematic review to identify and appraise the evidence for models of person-centred HIV care delivered in community care settings; systematic review findings then informed a topic guide for qualitative interviews. People living with HIV/AIDS (PLWHA) and healthcare professionals (HCP) were interviewed regarding HIV care, what PCC means in the African (Ghanaian) context and what person-centred outcomes matter to PLWHA. Interview findings were mapped onto a PCC theory in an expert intervention development workshop. A "community-based enhanced care intervention" (CECI) was developed and tested in a parallel mixed-methods feasibility cluster (2 clusters) randomised controlled trial (cRCT). Qualitative and quantitative data were analysed using NVivo version 12 and the SPSS version 25 respectively. Primary outcome was trial recruitment and retention.

Results: The systematic review revealed limited research on person-centred models of care in community settings, as the 5 studies retained in the final analysis only 2 delivered all four PCC components (physical, psychological, social and spiritual wellbeing). N= 24 PLWHA and 15 HCP were interviewed about HIV care delivery and their perspectives on PCC. The qualitative interviews revealed that PLWHA are not involved in their care and care does not address what mattered to them. HCP also lack skills to undertake holistic assessment and to practice PCC. These findings were integrated to form the key components of the CECI intervention. Of the 83 PLWHA screened for the feasibility cRCT, 60 were enrolled (30 participants assigned to each cluster). Recruitment and retention rates were 87% and 97% respectively. Potential effect size estimated at final timepoint for all measures using Partial Eta Squared statistics as a measure for

effect size and 95% confidence interval were: APCA POS [0.7 (95% CI 0.17 to 1.23) p<0.001]; MOS-HIV [0.7 (95% CI 0.17 to 1.23) p<0.001]; Picker Patient Experience Questionnaire (PPE-15) [0.8 (95% CI 0.27 to 1.31) p<0.001; CARE Measure [1.0 (95% CI 0.45 to 1.55) p<0.001], POSITIVE OUTCOMES [0.7 (95% CI 0.17 to 1.23) p<0.001]. Post-trial interviews revealed a general acceptability of the intervention including PLWHA feeling satisfied about their involvement in making decisions about their own care and their symptoms and concerns being assessed and addressed holistically using PCC. Training on the CECI was well received by HCP who felt equipped with skills to carry out holistic assessment and to practice PCC.

Conclusion: These findings indicate that PCC care is context-specific and contextual meaning of PCC should guide PCC intervention development to address what matters to PLWHA. The CECI was successfully implemented, it was feasible to recruit and retain participants in the trial and CECI was acceptable for both PLWHA and HCP. Results confirm the feasibility and justify a definitive cRCT of CECI to improve person-centred outcomes for PLWHA.

Candidate's statement of contribution and thesis originality

The concept of the PhD thesis arose from my interest in advancing palliative care practice in Ghana as a nurse working in a cancer treatment centre, and during the writing of my MSc dissertation when I developed a research proposal to integrate palliative care practice in HIV/AIDS care in community settings in Ghana. This research proposal won me a full PhD scholarship from the Ghana Education Trust Fund to undertake this PhD study.

I conceived the study aim and objectives, developed the study phased design and conducted each phase in this thesis including conducting a systematic review to identify and appraise the evidence for person-centred models of care in community HIV management and their impact on outcomes for people living with HIV/AIDS, development of the intervention and its feasibility testing. Within these study phases, I successfully wrote the qualitative and mixed methods feasibility cluster randomised controlled trial study protocols and projected budgets, obtaining ethical approval from Kings College London Research Ethics Committee, the Ghana Health Service Ethics Review Committee (GHS-ERC) and the Noguchi Memorial Institute for Medical Research Institutional Review Board (NMIMR-IRB) (Appendix A to F). I conducted all the qualitative interviews including training healthcare professionals to deliver the intervention and feasibility trial outcome data collection, alongside conducting the data analysis and interpretation. This thesis was written by me and presents my original thoughts and arguments, supervised and supported by my two supervisors.

This thesis was conducted while I was registered as a PhD student at Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care King's College London, with supervision from Professor Richard Harding and Dr Katherine Bristowe, with regular Thesis Progression Committee meetings (every 6 months) with two external advisors: Professor Irene Higginson and Dr Melanie Abas.

I have received tremendous support and help from colleagues in Cicely Saunders Institute while I was conducting this study in London. During the data collection period in Ghana, clinical staff including physicians, nurses, social workers, and allied health professionals in the Public Health Unit of the University of Ghana Hospital and the West Africa AIDS Foundation assisted me with

consent, recruitment and data collection in 2017 and 2018 respectively. This included helping in the dissemination of study information, setting up the environment for qualitative interviews and administrative work and providing precious comments and suggestions from their clinical experiences. I subsequently conducted the transcription and translation of the interviews, in preparation for analysis, and carried out all the analysis. All interpretations and conclusions are my own.

Table of Contents

ABSTRACT 2

CANDIDATE'S STATEMENT OF CONTRIBUTION AND THESIS ORIGINALITY 4

TABLE OF CONTENTS 6

TABLE OF FIGURES 12

TABLE OF TABLES 14

ACKNOWLEDGEMENTS 16

PUBLICATION AND PRESENTATIONS 17

ABBREVIATIONS 19

CHAPTER 1 INTRODUCTION AND BACKGROUND 20

1.1 INTRODUCTION 20

1.2 THESIS STRUCTURE 21

1.3 BACKGROUND 23

1.3.1 HIV/AIDS 23

1.3.2 HIV/AIDS epidemiology: Global, Africa and Ghana 24

1.3.3 HIV/AIDS burden in Ghana 25

1.3.4 HIV service delivery 26

1.3.5 Symptoms and concerns experienced by PLWHA 31

1.3.6 Holistic care 34

1.3.7 Person-centred approach as holistic care 35

1.3.8 Palliative care and person-centred care 38

1.3.9 Summary and rationale for the study 38

CHAPTER 2 AIM AND OBJECTIVES 40

2.1 AIM 40

2.2 OBJECTIVES 40

CHAPTER 3 METHODS 41

3.1 INTRODUCTION 41

3.2 Complex interventions 42
3.3 The MRC guidance 43
3.4 Mixed methods approach (pragmatism) 46
3.4.1 Rationale for using mixed methods design 46
3.4.2 Application of mixed methods design using the MRC guidance 47
3.4.3 Sequential explanatory design 48
3.5 The MRC guidance and the underpinning theoretical model 51
3.5.1 The Theory of Change 51
3.5.2 Adapting Person-centred care theory as the ToC 52
3.6 Setting, translations and ethics as applied to the whole study 54
3.6.1 Setting 54
3.6.2 Translations 57
3.6.3 Ethics 59
3.7 Data management and storage 62
3.8 Phase 1: Thesis objective 1 64
3.8.1 Design 64
3.8.2 Definition of terms 64
3.8.3 Search strategy 65
3.8.4 Inclusion and exclusion criteria 67
3.8.5 Data collection and extraction 67
3.8.6 Quality appraisal of studies included 68
3.8.7 Analysis 69
3.9 Phase 2: Thesis objective 2 71
3.9.1 Study design 71
3.9.2 Data analysis 77
3.9.3 Presenting the results 81
3.9.4 Trustworthiness in qualitative research 81
3.10 Phase 2: Thesis objective 3 87
3.10.1 Adaptation of Person-centred theory 87
3.10.2 Mapping person-centred care components onto person-centred theory 88

3.10.3 Integration of data from thesis objectives 1-3 89
3.11 PHASE 2: THESIS OBJECTIVE 4 90
3.11.1 Intervention development process 90
3.12 PHASE 3: THESIS OBJECTIVE 5 102
3.12.1 Feasibility trial registration 102
3.12.2 Feasibility outcomes 102
3.12.3 Feasibility studies 103
3.12.4 Quantitative component of the feasibility trial 103
3.12.5 Randomisation 106
3.12.6 Qualitative component of the feasibility trial 114
3.12.7 Data analysis 116
3.12.8 Rigour and data quality 120
3.12.9 Feasibility criteria for progressing to a definitive trial 121
3.12.10 Measures put in place to protect against bias 122
3.12.11 Refining the intervention using the data generated and the logic model 123
CHAPTER 4 RESULTS 1. PHASE 1 (THESIS OBJECTIVE 1) 124
4.1 SYSTEMATIC REVIEW 124
4.1.1 Study characteristics 124
4.1.2 Person-centred care models 125
4.1.3 Details of PCC components delivered 126
4.1.4 Using the Donabedian framework of healthcare quality 135
4.1.5 Summary 137
CHAPTER 5 RESULTS 2. PHASES 2 (THESIS OBJECTIVES 2, 3 AND 4) 139
5.1 PHASE 2. THESIS OBJECTIVES 2, 3 AND 4: QUALITATIVE INTERVIEW 139
5.2 THESIS OBJECTIVE 2 140
5.2.1 Details of participants recruited for interviews 140
5.2.2 Achievement of purposive sampling frame for PLWHA 142
5.2.3 The interview processes 147
5.2.4 Thematic framework 149

5.3 THESIS OBJECTIVE 3 FINDINGS 163
5.3.1 Mapping the qualitative data onto the theory of PCC 163
5.3.2 Implication for intervention development 165
5.3.3 Framework to inform PCC delivery 166
5.4 THESIS OBJECTIVE 4 FINDINGS ("MODELLING PROCESS AND OUTCOMES") 168
5.4.1 Main findings from thesis objectives 1, 2 and 3 168
5.4.2 Results from expert intervention development workshop 169
CHAPTER 6 RESULTS 3. PHASE 3 (THESIS OBJECTIVE 5) 179
6.1 MIXED METHODS FEASIBILITY TESTING OF CECI 179
6.1.1 Primary and secondary outcomes 180
6.1.2 Participating clinics 180
6.1.3 Screening and recruitment 180
6.1.4 Baseline and clinical data collection 183
6.1.5 Secondary outcomes 185
6.1.6 CECI training for HCP at the intervention site 185
6.1.7 Follow up 189
6.1.8 Intervention implementation fidelity and adherence 190
6.2 SUMMARY OF FEASIBILITY FINDINGS 191
6.3 OUTCOME MEASURES 192
6.3.1 Missing data 192
6.3.2 Outcome measures and time to complete 194
6.3.3 Potential effect sizes 196
6.3.4 Comparison of outcome measure mean scores for control and intervention arms 197
6.4 POST-TRIAL QUALITATIVE INTERVIEW FINDINGS ON CECI ACCEPTABILITY 202
6.4.1 Sample characteristics 202
6.4.2 Coding framework 203
6.4.3 Summary of post-trial interview findings 213
CHAPTER 7 DISCUSSION 215
7.1 SUMMARY OF MAIN FINDINGS 215

7.2 STUDY AIM 216
7.3 SUMMARY OF OBJECTIVES 216
7.3.1 Objective 1 (Systematic review of PCC models of community HIV management) 216
7.3.2 Thesis objective 2 (Qualitative interviews to inform intervention development) 217
7.3.3 Thesis objective 3 (Mapping qualitative data onto components of PCC theory) 219
7.3.4 Thesis objective 4 220
7.3.5 Thesis objective 5 221
7.4 METHODOLOGICAL CONSIDERATIONS 223
7.4.1 Feasibility studies 223
7.4.2 Cluster randomised controlled trials 223
7.4.3 Recruitment and retention 224
7.4.4 Intervention delivery and outcome 225
7.4.5 Incidental benefits derived from completing measures 225
7.5 COMMUNICATION IN HEALTHCARE 226
7.6 STRENGTH AND LIMITATIONS 227
7.7 IMPLICATION FOR PRACTICE, POLICY AND RESEARCH 229
7.7.1 Implication for clinical practice 229
7.7.2 Implication for policy 231
7.7.3 Future direction of research in this area 232
7.8 PERSONAL LEARNING AND REFLECTION 234
7.9 CONCLUSION 237
REFERENCES 240
APPENDIX A. KCL ETHICS APPROVAL FOR STUDY PHASE 2 266
APPENDIX B. GHS ETHICS APPROVAL FOR STUDY PHASE 2 267
APPENDIX C. NOGUCHI ETHICS APPROVAL FOR STUDY PHASE 2 268
APPENDIX D. KCL ETHICS APPROVAL FOR STUDY PHASE 3 269
APPENDIX E. GHS ETHICS APPROVAL FOR STUDY PHASE 3 270
APPENDIX F. NOGUCHI ETHICS APPROVAL FOR STUDY PHASE 3 271

APPENDIX G. PLWHA PARTICIPANT INFORMATION FOR STUDY PHASE 2 272
APPENDIX H. PLWHA CONSENT FORM FOR STUDY PHASE 2 275
APPENDIX I. HCP PARTICIPANT INFORMATION FOR STUDY PHASE 2 277
APPENDIX J. HCP CONSENT FORM FOR STUDY PHASE 2 280
APPENDIX K. PLWHA INTERVIEW GUIDE FOR STUDY PHASE 2 282
APPENDIX L. HCP INTERVIEW GUIDE FOR STUDY PHASE 2 286
APPENDIX M. INTERVENTION TRAINING CONTENT 290
APPENDIX N. HOLISTIC ASSESSMENT TOOL FOR STUDY PHASE 3 327
APPENDIX O. CARE PLAN TEMPLATE USED TO PLAN CARE FOR STUDY PHASE 3 .. 334
APPENDIX P. PLWHA PARTICIPANT INFORMATION FOR STUDY PHASE 3 335
APPENDIX Q. PLWHA CONSENT FORM FOR STUDY PHASE 3 339
APPENDIX R. PARTICIPANT SCREENING LOG FOR STUDY PHASE 3 341
APPENDIX S. INTERVENTION TRAINING CERTIFICATES 345
APPENDIX T. DATA COLLECTION TOOLS FOR STUDY PHASE 3 347
APPENDIX U. PLWHA INFORMATION FOR POST-TRIAL INTERVIEW 362
APPENDIX V. PLWHA CONSENT FORM FOR POST-TRIAL INTERVIEW 366
APPENDIX W. HCP INFORMATION ON POST-TRIAL INTERVIEW 368
APPENDIX X. CONSENT FORM FOR HCP POST-TRIAL INTERVIEWS 371
APPENDIX Y. POST-TRIAL INTERVIEW GUIDE FOR INTERVENTION ARM 373
APPENDIX Z. POST-TRIAL INTERVIEW GUIDE FOR HCP 375
APPENDIX AA. POST-TRIAL INTERVIEW GUIDE FOR CONTROL ARM 377
APPENDIX BB. PUBLISHED QUALITATIVE PAPER FOR THESIS PHASE 2 380
APPENDIX CC. PUBLISHED FEASIBILITY CRCT PAPER FOR THESIS PHASE 3 391
APPENDIX DD. SYSTEMATIC REVIEW MANUSCRIPT FOR THESIS PHASE 1 404
APPENDIX EE. GNATT CHART SHOWING PHD KEY MILESTONES 431

Table of Figures

Figure 1: Stages of HIV infection, adapted from AIDSinfo and CDC [46, 47] 23
Figure 2: Ghana's HIV treatment cascade showing 90-90-90 targets progress [52] 26
Figure 3: Map of Ghana showing the ten administrative regions [89] 29
Figure 4: Conceptual framework for feasibility studies, adapted from Eldridge et al. [177] 42
Figure 5: The four research stages of the MRC guidance adapted from Craig et al. [176].....45
Figure 6: The Development and Feasibility stages of the MRC guidance mapped onto study objectives 46
Figure 7: Study overview with thesis objectives incorporated within the development and feasibility stages of the MRC guidance 50
Figure 8: The integration of Theory of change into the MRC guidance for complex interventions, adapted from De Silva et al. [213] 52
Figure 9: Location of study settings showing drive time distance between the two clusters.....57
Figure 10: The components of person-centred theory as defined by Mezzich [146] 88
Figure 11: Feasibility cRCT flow diagram 105
Figure 12: CECI training underway 108
Figure 13: Diagram on intervention training 109
Figure 14: CECI supervision meeting underway 111
Figure 15: PRISMA flow diagram 125
Figure 16: Qualitative intervention development stage of the MRC guidance 139
Figure 17: A conceptual model of person-centred care from the perspectives of PLWHA and HCP in Ghana 160
Figure 18: Qualitative data mapped onto components of PCC theory 164
Figure 19: Process and outcome measures mapped onto components of PCC theory 164
Figure 20: Framework to inform PCC delivery incorporated into the WHO's framework on integrated people-centred health services 167
Figure 21: Logic model of CECI with detailed components relating to context, training, implementation, mechanism of action and outcomes 172
Figure 22: A graphical depiction of CECI with its sequential steps of implementation.....173
Figure 23: CECI care process with PCC as the ToC 178
Figure 24: Feasibility cluster RCT of CECI as situated in the overall study plan 179

Figure 25: Accrual by clinic per week.....181
Figure 26: CONSORT extension for feasibility trials - flow diagram 183
Figure 27: APCA POS mean scores plotted for control and intervention arms.....197
Figure 28: MOS-HIV mean scores plotted for control and intervention arms.....198
Figure 29: POSITIVE OUTCOMES mean scores plotted for control and intervention arms.....199
Figure 30: CAREM mean scores plotted for control and intervention arms 200
Figure 31: PPE-15 mean scores plotted for control and intervention arms.....201

Table of Tables

Table 1: Global HIV statistics for the year 2018 [1] 24

Table 2: SSA and Ghana HIV estimates for year 2018 [1] 25

Table 3: Concepts of PCC described in literature with specific components of delivery 36

Table 4: Characteristics of study sites 56

Table 5: Preliminary literature search using the search strategy 66

Table 6: Review inclusion and exclusion criteria 67

Table 7: Quality domains assessed for quantitative studies, adapted from Kmet et al. [244] 68

Table 8: Quality domains assessed for qualitative studies 69

Table 9: Sampling framework for recruiting PLWHA 74

Table 10: Data collection and timepoints n=30 112

Table 11: Detailed comparison of CECI and SHC to timelines and timing of CECI delivery 113

Table 12: Template for reporting summary of missing data 118

Table 13: PCC components delivered in studies retained as mapped onto Mezzich's [146] domains 126

Table 14: Data extraction table (n=5 papers) 128

Table 15: Interview participants recruitment details 140

Table 16: Summary of participant characteristics n=39 141

Table 17: Details of how the a priori sampling criteria were met 142

Table 18: Details of sampling criteria recruited n=24 144

Table 19: Details of HCP participant sampled n=15 147

Table 20: Intervention training content and schedule for HCP 174

Table 21: Person-centred domains described by participants mapped onto selected outcome measures 175

Table 22: Process of care delivery described by participants mapped onto selected process measures 176

Table 23: Records of participant screening and recruitment 181

Table 24: Baseline and clinical characteristics 184

Table 25: Details of HCP who attended the CECI training 186

Table 26: Details of intervention appointments attended 187

Table 27: Follow up rates 190

Table 28: CECI fidelity checklist.....190
Table 29:Primary outcome findings.....191
Table 30: Summary of missing data from outcome measures by timepoint and trial arm 192
Table 31: Data completeness for completed measures by timepoint 193
Table 32: Mean scores with corresponding standard deviations 195
Table 33: Change scores with potential effect sizes and confident intervals estimated at Time 3 195
Table 34: Mean scores with corresponding standard deviations for the process measures.....195
Table 35: Change scores with potential effect sizes and confident intervals 196
Table 36: Potential effect size estimates by measure.....196
Table 37:Sample characteristics for the entire feasibility cRCT and the post-trial interviews ...202
Table 38: Sample characteristics for HCP who were interviewed in the CECI arm 203

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Publication and presentations

Research publication and manuscripts under review

Mary Abboah-Offei, Katherine Bristowe, Jonathan Koffman, Naa Ashiley Vanderpuye-Donton, Gloria Ansa, Melanie Abas, Irene Higginson & Richard Harding (2019): How can we achieve person-centred care for people living with HIV/AIDS? A qualitative interview study with healthcare professionals and patients in Ghana, AIDS Care, DOI: 10.1080/09540121.2019.1698708: **see Appendix BB**

Mary Abboah-Offei, Katherine Bristowe, Naa Ashiley Vanderpuye-Donton, Gloria Ansa, Oppong-Agyei Yaa, Melanie Abas, Irene Higginson & Richard Harding (2020): Phase II mixed methods feasibility cluster randomised controlled trial of a novel community-based enhanced care intervention to improve person-centred outcomes for people living with HIV in Ghana, AIDS Care, DOI: 10.1080/09540121.2020.1739217: see **APPENDIX CC**

Mary Abboah-Offei, Katherine Bristowe & Richard Harding (**under review**): Are patient outcomes improved by models of community HIV management which aim to be person-centred? A systematic review of the evidence, AIDS Care: see **APPENDIX DD**

Research conference presentations at scientific meetings

Mary Abboah-Offei, Katherine Bristowe, Jonathan Koffman, Melanie Abas, Irene Higginson & Richard Harding (2018): A Systematic Review of the Evidence for Community and Person-centred Models of Care and their Impact on Outcomes for People Living with HIV/AIDS. 10th World Research Congress of the European Association for Palliative Care (**poster presentation**), 24-26 May 2018, Bern, Switzerland.

Mary Abboah-Offei, Katherine Bristowe, Jonathan Koffman, Naa Ashiley Vanderpuye-Donton, Gloria Ansa, Melanie Abas, Irene Higginson & Richard Harding (2019): How Can We Achieve Person-centred Care for People Living with HIVAIDS? A Qualitative Study of Healthcare Professionals and Patients in Ghana. 16th World Congress of the European Association for Palliative Care (**poster presentation**), 23-25 May 2019, Berlin, Germany.

Mary Abboah-Offei, Katherine Bristowe, Jonathan Koffman, Naa Ashiley Vanderpuye-Donton, Gloria Ansa, Melanie Abas, Irene Higginson & Richard Harding (2019): Phase II Mixed Methods Feasibility Cluster Randomised Controlled Trial of a Novel Community-based Enhanced Care Intervention to improve person-centred outcomes for People Living with HIV/AIDS in Ghana. AIDSImpact 14th International Conference (**oral presentation**), 29-31st July 2019, London, United Kingdom.

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Abbreviations

Abbreviation	Meaning
AIDS	Acquired Immunodeficiency Syndrome
APCA	African Palliative Care Association
POS	Palliative care Outcome Scale
HIV	Human Immunodeficiency Virus
PLWHA	People Living With HIV/AIDS
PCC	Person-centred care
PO	Positive Outcomes
KCL	King's College London
GHS	Ghana Health Service
PROM	Patient reported outcome measure
PPE-15	Picker Patient Experience Questionnaire
CAREM	Consultation and relational empathy measure
MOS-HIV	Medical Outcome Study-HIV Health Survey
UNAIDS	The Joint United Nations Programme on HIV and AIDS
CECI	Community-based enhanced care intervention
SHC	Standard HIV care
ART	Antiretroviral therapy
CDC	Centers for Disease Control and Prevention
SSA	Sub-Saharan Africa
cRCT	Cluster randomised controlled trial
WHO	World Health Organisation
HCP	Healthcare professionals
SPSS	Statistical Package for Social Sciences
CI	Confidence Interval
CD4	Cluster of differentiation 4
TB	Tuberculosis
CBHS	Community-based health services
GAC	Ghana AIDS Commission
CHBC	Community and home-based care
IOM	Institute of Medicine
MRC	Medical Research Council
CONSORT	Consolidated Standards of Reporting Trials
ISRCTN	International Standard Randomised Controlled Trials Number
ToC	Theory of Change
WAAF	West African AIDS Foundation
NGO	Non-governmental organization
MSM	Men who have sex with men
WSW	Women who have sex with women
DPA	Data Protection Act
GDPR	General Data Protection Regulation
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
COREQ	Consolidated criteria for reporting qualitative research
PROM	Patient reported outcome measure
TOPCare	Treatment outcomes in palliative care
ANCOVA	Analysis of covariance

Chapter 1 Introduction and background

1.1 Introduction

There are approximately 37.9 million people living with HIV/AIDS (PLWHA) globally [1]. PLWHA experience diverse problems throughout the disease trajectory, including physical pain [2] and other symptoms [3, 4]. Evidence suggests that pain experienced by PLWHA impacts on retention in care, adherence, and consequently viral load suppression, and physical function [5-8]. Also, PLWHA experience psychological and physical symptoms even after commencement of antiretroviral therapy (ART) [9-15]. PLWHA also experience social isolation [16], spiritual distress [17], and their significant others also endure emotional [18] and financial [19] hardships. It has been revealed that disclosing HIV/AIDS status can result in adverse personal outcomes such as loss of relationships and social rejection [20].

Currently, PLWHA on ART have higher prevalence of depression, anxiety and worse health-related quality of life than the general population [14, 15, 21]. Evidence from Africa suggests that, 44-58% of PLWHA irrespective of their treatment status, experience depression and other psychological problems [22]. Research has recognised a negative correlation between depression and adherence which, could pose a real threat to global successes of reducing the AIDS epidemic [23, 24]. Therefore, failure to manage these psychosocial and other problems experienced by PLWHA could result in serious clinical implications, including increased treatment failure and viral replication [25].

The WHO's "Global strategy on integrated people-centred health services 2016-2026", has called for the reorientation of care models to prioritise primary and community care services, and delivers holistic and comprehensive care that is sensitive to the needs of each individual [26]. Person-centred care has been recognised as one fast-track action to achieve the 90/90/90 targets set by the World Health Organisation (WHO) [27], and can be defined as care that focuses on the whole person, incorporating high quality care that addresses what matters to that individual [28-34]. Although person-centred care is a global goal, there is no agreed international definition [35-38], and it has not been explored in the African context [39].

Person-centredness must underpin interventions for PLWHA to remain in care and achieve optimal health [40]. This study is conceptually underpinned by the theory of person-centred care. Person-centred care is a central pillar to recent moves to enhance global HIV care and support [41-43], as it enables healthcare professionals to holistically assess the needs of PLWHA, and to initiate management strategies that reflect the interaction between physical, psychological, social and spiritual wellbeing. Retention in HIV/AIDS care, adherence and satisfaction with HIV/AIDS care could be informed by a better understanding of these four dimensions of wellbeing in relation to these outcomes.

1.2 Thesis structure

Chapter one of this thesis comprises the introduction and background of the study, which provides the reader with a justification for conducting the study including the overview of the thesis and the contextual background of HIV/AIDS. It describes the global, HIV/AIDS epidemiology including that of the sub-Saharan region and Ghana. This chapter includes a description of the healthcare delivery system in Ghana and challenges faced in delivering care to PLWHA. HIV symptom burden, models of HIV care delivery, rationale for focusing on community models of care, holistic care and the need for person-centred care for PLWHA is also outlined in this chapter.

Chapter two presents the aim and objectives of the thesis.

Chapter three details the study methods including a discussion of the design rationale for the study design. This chapter is organised by thesis objective and the corresponding methods. The first section of chapter three describes the study phases, complex intervention, the MRC guidance and the use of theory of change. It then describes the setting where the study was conducted including ethical considerations made in relation to the design and implementation of the study contents. The methods include a systematic review which informed qualitative interviews with PLWHA and healthcare professionals (HCP), intervention development, the feasibility cluster randomised controlled trial (cRCT) comprising quantitative outcome data collection and a post-trial exit qualitative interview.

Chapter four presents the findings for the first stage of the MRC complex interventions guidance, i.e. results of the systematic review that appraised the evidence for person-centred care models of HIV care delivered in community settings. This includes the PRISMA flow diagram showing the number of studies retrieved and the number retained for final analysis, data extraction table, study quality assessment and the person-centred components within the models. It then critically reviews and appraises studies conducted in both developed and developing countries.

Chapter five reports the results of the qualitative interviews with HCP and PLWHA, and the intervention development.

Chapter six reports the results of the feasibility cRCT including recruitment and participants flow through the trial, baseline data characteristics of study participants of the two parallel groups, uptake and adherence of the intervention. Primary and secondary outcomes are discussed including the feasibility and acceptability of the intervention.

Chapter seven appraises the strengths and limitations of the study including the qualitative intervention development components of the feasibility cRCT comparing findings to other studies conducted elsewhere in HIV populations. Finally, this chapter discusses the implications of person-centred intervention for practice, policy and training for HIV/AIDS care as well as recommendations for future research.

1.3 Background

1.3.1 HIV/AIDS

The surveillance definition for AIDS is acquired immunodeficiency syndrome, which is based on the signs, symptoms, infections, and associated cancers that comes with the deficiency of the immune system as a result of HIV infection [44]. A human retrovirus which causes this life-threatening immunodeficiency syndrome is the Human Immunodeficiency Virus (HIV) [44]. The first AIDS cases were reported in 1981 in the USA and it remains a disease of public health importance existing for more than three decades [45]. The cells of the human immune system infected by the retrovirus are mainly the CD4 T-cells and macrophage, which are the key components of the cellular immune system that this virus infects, destroys and impairs the function of the immune system [44]. HIV has no cure. However, treatment with antiretroviral therapy (ART) slows or prevents HIV from progressing to AIDS. The main aim of the ART is to assist persons infected with the HIV virus by reducing their viral load to an undetectable level for them to live healthier and longer lives. When the level of HIV in the blood is too low to be detected by a viral load test it is referred to as an “undetectable” level, and maintaining this level means that the virus cannot be transmitted to others [46]. The Centers for Disease Control and Prevention (CDC) classified HIV infection into three stages including acute and chronic infection, and AIDS [46, 47] (see Figure 1).

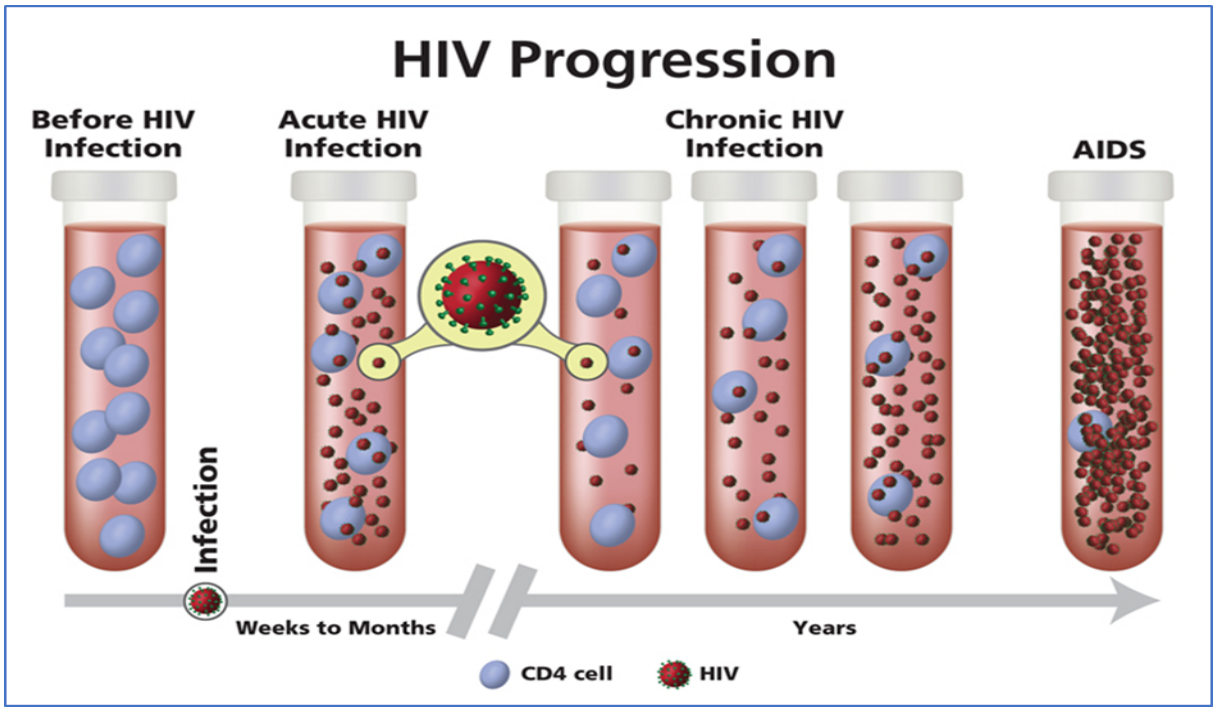


Figure 1: Stages of HIV infection, adapted from AIDSinfo and CDC [46, 47]

1.3.2 HIV/AIDS epidemiology: Global, Africa and Ghana

In 2018 an estimated 37.9 million people globally (36.2 million adults and 1.7 million children under age 15) were living with HIV, with approximately 23.3 million receiving ART, showing a 15.6 million increase in those accessing treatment from 7.7 million in 2010. The year 2018 also saw 1.7 million new infections compared to 2.9 million in 1997 (a reduction of 40% since the peak in 1997). This was due to global expansion in education and scale up in ART treatment, which also resulted in around 770,000 AIDS-related deaths compared to 1.7 million and 1.2 million deaths in 2004 and 2010 respectively (approximately 55% reduction in death since 2004) [1]. Approximately 74.9 million people have become infected with HIV (of which about 8.1 million did not know they were living with HIV), and about 32 million have died from AIDS-related causes since the start of the epidemic [1]. UNAIDS set the 90-90-90 targets to ensure that 90% of people living with HIV know their HIV status; 90% of people with positive HIV status are put on ART; and 90% of people on ART should be virally suppressed [48]. By 2018, 79% of people living with HIV knew their status; 78% of people who knew their status were accessing treatment; 86% of people accessing treatment were virally suppressed [1], from the UNAIDS 90-90-90 treatment targets set [49]. The global HIV estimates have been summarised in Table 1.

Table 1: Global HIV statistics for the year 2018 [1]

Item	**Estimate**
People living with HIV	37.9 million
Adults (> 15 years)	36.2 million
Children (<15 years)	1.7 million
People accessing treatment	23.3 million
New infections	1.7 million
Deaths	770000
Progress towards 90-90-90	
People who knew their status	79%
People accessing treatment from knowing their status	78%
People virally suppressed from accessing treatment	86%

Of the global HIV estimate for the year 2018, the vast majority of PLWHA were from Eastern and Southern Africa (the most HIV/AIDS affected region), which had an estimated 20.6 million PLWHA with 13.8 million accessing treatment; and Western and central Africa (the 3rd most affected region) with approximately 5.0 million PLWHA and an estimated 2.6 million receiving treatment

[1]. This makes Sub-Saharan Africa (SSA) the most affected region and home to approximately 25.6 million (68%) of all PLWHA globally, of which 16.4 million were accessing treatment and about 470,000 died from AIDS-related disease [1]. Table 2 is a summary of the 2018 estimates for SSA and Ghana.

Table 2: SSA and Ghana HIV estimates for year 2018 [1]

Item	**Estimate**	**Proportion of global estimate**
SSA		
People living with HIV	25.6 million	68%
New infections	1.08 million	
People accessing treatment	16.4 million	
Deaths	470,000	
Ghana		
People living with HIV	330,000	
New infections	20,000	
People accessing treatment	110,000	
Deaths	14,000	

1.3.3 HIV/AIDS burden in Ghana

Compared to most countries within Eastern and Southern Africa, countries within Western Africa face relatively low HIV prevalence levels. Ghana, one of the 49 countries in sub-Saharan region of Western Africa, as well as one of the largest countries in West Africa in terms of population size, had an adult HIV prevalence of 1.7% in 2018 [50], this prevalence is a marked reduction from 3.7% at the initial stages of the pandemic [51]. Current estimates show that, of the 90-90-90 targets set by the UNAIDS [48], Ghana currently have 55% of PLWHA who know their status and 34% who know their HIV status are on treatment and 23% who are on treatment are virally supressed [52] (see Figure 2). With the 90-90-90 treatment targets deadline fast approaching, Ghana's performance on the second and third '90' is very poor and this has been attributed to stigma and discrimination which continue to prevent PLWHA from accessing treatment [53]. There is a call to fight against stigma to allow PLWHA to access services freely, in addition to delivering HIV care services at the community level in order to close the vast gap between Ghana's performance towards achieving the 90-90-90 [53].

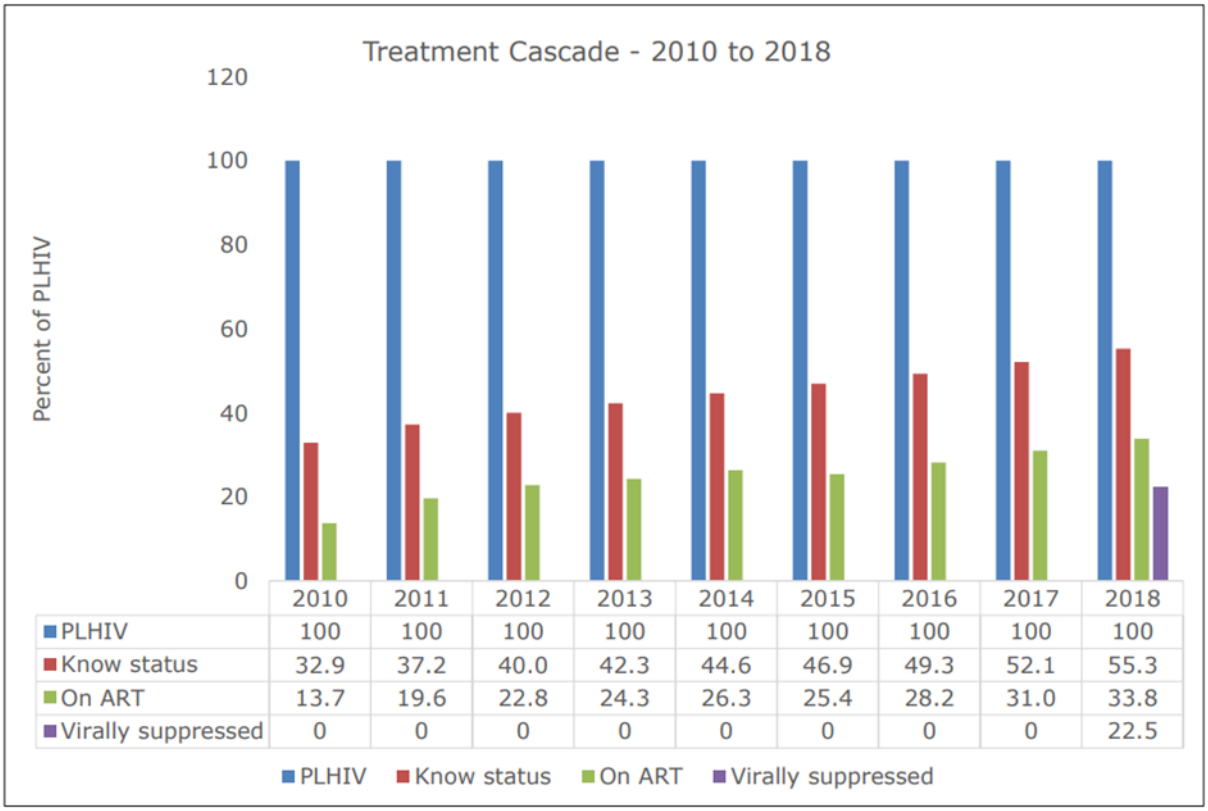


Figure 2: Ghana's HIV treatment cascade showing 90-90-90 targets progress [52]

1.3.4 HIV service delivery

PLWHA require access to care and support services to improve their quality of life and community-based care is an important alternative when hospital care becomes neither necessary nor desirable. Prolong waiting time before seeing a doctor at the hospital continues to be a matter of concern [54], therefore an alternative for patients is to self-medicate, resulting in attendance to community pharmacies as their first point of call when sick [55]. Taking into consideration the increasing number of PLWHA who default, in addition to the aim to achieve the 90-90-90 targets set by UNAIDS [48], people continue to advocate for more services to be accessible including at the community level where PLWHA can receive high quality care. Home and community care services for PLWHA have already gained international recognition [56]. As a result of the 90-90-90 global campaigns, the number of people aware of their HIV status continue to increase as does the need for continuity of care.

1.3.4.1 Community HIV care delivery

The scale of the HIV/AIDS epidemic has resulted in decentralization of HIV services through community-based approaches, which have been used in many regions with limited healthcare resources, in order to overcome the challenges imposed by HIV/AIDS [57, 58]. Although the components of community-based care services are common across settings [59, 60], the specification of a given model is dependent on contextual factors, which include national policies, available resources and non-governmental organizations. Community-based programs that address various aspects of the HIV/AIDS continuum of care were introduced in countries affected by the epidemic in the 1990s [61, 62]. There is currently a challenge of delivering treatment to those in need and providing care for those on life-long treatment [63-65]. Consequently, health planners have shown renewed interest in the potential role of community-based programs and community health workers in ART monitoring, so as to increase access to ART with scarce health professional resources [66].

Evidence suggest that physician-focused models of care in most contexts have been replaced with trained non-physician health worker models [57, 64, 67]. For instance, the nurse-led ART program in Lesotho [67], the community-based Health Surveillance Assistants dispensing ART and monitoring of patients who are stable in a region of Malawi, and the Kenyan community care coordinators [57]. Community-based care services have been shown to increase access to essential programs for PLWHA and their families through the mobilization of community interests and resources [68]. Evidence affirms that community-based care services could promote awareness, at the same time reduce stigma and the burden on the primary-care system, and eventually cause a reduction in the incidence of hospitalization [69, 70]. Available data suggests that at least in some contexts, adherence and viral load suppression could be enhanced in community-based care services relative to hospital-based care [71, 72].

Meanwhile, with the increase of ART coverage in many contexts, consideration of community-based care services has become crucial [73]. UNAIDS emphasises the potential role for community service delivery and has strategised increased access to care by delivering 30% of HIV care in community settings [74]. Community services have played significant roles as part of the comprehensive HIV response of many nations [75]. The WHO defined community-based health services (CBHS) as “all services provided by people who spend a substantial part of their working time outside a health facility, discharging their services at the individual, family or

community level, as well as primary health care services provided in small local health facilities. The exact boundaries of the definition will differ from country to country" [76]. Two distinct groups provide CBHS: formally-trained healthcare professionals (nurses, public health inspectors, health visitors, doctors etc.), and community health workers (volunteers, peers etc.) [76].

There is evidence that community-based care initiatives for PLWHA help to relieve HIV related-symptoms including psychosocial problems, thereby improving quality of life [77-82]. The WHO's "Global strategy on integrated people-centred health services 2016-2026", has called for the reorientation of care models that prioritise primary and community care services, and deliver holistic and comprehensive care that is sensitive to the needs of individuals [26]. Delivering such care in a more decentralized manner [83] could facilitate easy access to care, including one-stop care and expansion of appointment times for working PLWHA [84]. In order to develop care interventions that could optimally provide holistic care for PLWHA, this study used a community-based approach with a key focus on person-centredness [40].

1.3.4.2 HIV service delivery in Ghana

Ghana is administratively divided into ten regions (see Figure 3), with the Greater Accra region being the capital of Ghana [85]. The country operates a decentralised structure following a four-tier system: national, regional, district, and sub-district levels. Health delivery is also decentralised and structured with the community level being the first point of the primary health care system operating at the sub-district level with clinics and health centres often staffed by nurses and mainly led by Physician Assistants. Hospitals at the district and regional levels are led by medical officers who provide the secondary level of care. Teaching hospitals operate at the tertiary level with locations including the Northern, Ashanti, Greater Accra, and Central regions of Ghana [86, 87]. HIV services are structured along the formal health system with facilities providing all services including referral of clients along the continuum of care, and these referrals are done based on the hierarchy of care delivery in Ghana: primary, secondary and tertiary levels [88]. Referring to the various levels of care delivery is dependent on the skill of the service provider, logistics available and sometimes proximity of the health facility according to ART guidelines for Ghana [88].

Figure 3: Map of Ghana showing the ten administrative regions [89]

Since the identification of the first HIV case in 1986, Ghana has been providing HIV-related services including the addition and expansion of services along the continuum over the past

decades and ART services being added to its comprehensive care in 2003 [88]. Ghana has in place all relevant policies and programs through its National HIV response in promoting the entire continuum of HIV services and care. However, community home based care (CHBC) appeared to have been abandoned with CHBC activities carried out in a policy vacuum, with no proven mechanisms for coordination nor standardized training of service providers. Consequently, the Ghana AIDS Commission (GAC) in partnership with stakeholders developed CHBC policy and a country-specific guideline to inform harmonised HIV service delivery in the community. A national strategy and guidelines are critical to guide the implementation of CHBC interventions in Ghana, which are at their nascent stage [90].

Due to the devastating socio-economic impact of HIV infection (stigma faced, impact on employment status, family income and expenditure, availability of care and support service), coupled with insufficient resources at health facilities, PLWHA have limited access to the appropriate care in Ghana [90]. Also, most patients delay attendance to health facilities until their symptoms become severe leading to late presentations, when curative treatment is often not an option [91]; whereas others resort to the use of informal health services such as attending prayer camps and visiting traditional healers [92] among others. Traditional healers are important in resource-limited countries including Ghana because they are readily available, affordable, and they serve as the main source of healthcare in most rural communities [93]. It has been reported that an estimated 70% of Ghanaians rely on traditional remedies for their healthcare needs [94, 95]. Also, evidence suggest that some PLWHA use traditional healers whiles on ART, because the care they receive from these healers is affordable and culturally acceptable [96, 97]. Therefore, it appears there is the need to consider incorporating traditional healers in HIV/AIDS care through appropriate education if care provision in the community will be a success.

1.3.4.3 Nursing education/ training in Ghana

Nurses trained in Ghana receive comprehensive training on human anatomy and physiology, pharmacology, nutrition and dietetics, community, psychiatric, paediatrics, obstetrics, medical and surgical nursing, in addition to psychology among others [98]. The medical focus of undergraduate nurse training curriculum for nurses attending the University of Ghana [98], suggests a general lack of prioritisation of psychosocial and spiritual needs due to the dominance of biomedical discourse among HCP and the necessary rationalisation of HCP time due to the volume of

patients seen per day. This is compatible with findings from Gott et al. [99], that the dominance of the biomedical discourse and its associated focus on 'cure' as the only legitimate approach to care is a barrier to the delivery of holistic palliative care at any time but the terminal phase of life. In settings where this philosophy of cure is the strongest legitimate form of care, it is likely that the perspectives of professionals from primary health [100] and nursing [101], with a more established record of holistic multidimensional approaches to care, would be less well received. The implementation of a short training package in person-centred care for HCP may help them recognise the importance of attending to patients' psychosocial and spiritual problems, and how this contributes to holistic wellbeing in PLWHA.

1.3.5 Symptoms and concerns experienced by PLWHA

PLWHA frequently experience highly distressing physical, psychological, social and spiritual symptoms and concerns [5, 102-104] which negatively impact upon their quality of life [105]. Greatest attention has been paid to viral suppression at the expense of broader psychological, social and spiritual concerns that persist despite treatment advances [5, 106]. It should be noted that there is an interaction between symptoms experienced by PLWHA, e.g. pain can lead to depression; psychological problems such as anxiety and depression can worsen many symptoms, e.g. pain, breathlessness; social problems, e.g. lack of income or loss of careers, affects physical and psychological wellbeing; and spiritual issues affect psychological and social wellbeing [107]. Therefore, the care delivered to PLWHA should take into consideration these four domains of need including physical psychological, social and spiritual in order to manage their needs holistically. Dame Cicely Saunders, also suggested that pain should be understood as having physical, psychological, social and spiritual elements [108], a combination of which results in 'total pain' experience that is specific to every individual patient's situation. Simms et al. [109] argued that, the holism and person-centeredness that characterised HIV care in the pre-ART era appeared to have been lost, re-echoing the importance of person-centred care in HIV/AIDS management.

1.3.5.1 Physical symptoms experienced by PLWHA

PLWHA experience diverse problems throughout the disease trajectory, including physical pain [2] and other symptoms [3, 4]. Although the availability of ARTs in low and middle income countries continue to prolong the lives of PLWHA, symptoms of pain continue to affect a

significant proportion of PLWHA [110]. Evidence suggest that between 29% to 74% of people who receive ART experience pain symptoms [9, 111-114]. Pain is a common symptom reported by PLWHA, although the exact cause has not been thoroughly described, pain in PLWHA has been attributed to HIV disease symptom, opportunistic infections and side effects of ARTs [112, 115]. Different anatomic sites have been associated with HIV-related pain [116], including headache, peripheral neuropathy, joint pain muscle pain, abdominal pain, bone pain and herpes-related pain [115]. It has been estimated that 39%–85% of PLWHA experience chronic pain compared with 20%–30% of general population [117]. Evidence suggests that pain experienced by PLWHA impacts on their wellbeing, quality of life and physical function [5-8].

1.3.5.2 Psychological symptoms experienced by PLWHA

Evidence from Africa suggests that, 44-58% of PLWHA irrespective of their treatment status, commonly experience depression and other psychological problems [22]. Also, research has recognised a negative correlation between depression and adherence which, could pose a real threat to global successes of reducing the AIDS epidemic [23, 24]. There is increased risk of developing mental health conditions among PLWHA [118, 119], which could undermine their health seeking behaviours and reduce adherence to treatment [120] leading to higher rates of mortality [121-123] . The most common mental health conditions that co-occur with HIV are depression and anxiety; a meta-analysis of studies conducted in sub-Saharan Africa revealed a 24% prevalence of depression among PLWHA [118]. PLWHA can experience depression and anxiety as they adapt to living with HIV/AIDS or anticipating stigma or managing ongoing life stressors [124]. Among the predicting factors of depression include unemployment, negative life events, greater number of HIV-related physical symptoms, low CD4 counts, impaired function and poor social support [122, 125]. Having access to HIV care and treatment including mental health services is essential in supporting quality of life. However, even after achieving viral suppression, PLWHA may still report lower quality of life than the general population, with depression and anxiety contributing significantly to these outcomes [21].

1.3.5.3 Social concerns of PLWHA

PLWHA experience social isolation [16] with their significant others also enduring emotional [18] and financial [19] hardships. It has been revealed that, disclosing HIV/AIDS status can result in adverse personal outcomes such as loss of relationships and social rejection [20]. HIV-related

stigma has been extensively reported and feared by PLWHA and may be in addition to actual or perceived stigma associated with their gender, religion, ethnicity and sexuality [15, 126]. Stigma has been described as any form of negative attitude, prejudice, discrimination or abuse suffered by PLWHA as a result of their HIV status [126, 127]. Living with HIV/AIDS at the family level severely compromises household resources as the functional capacity to work is reduced, with increasing medical expenditures and the income of both the PLWHA and others affected [128, 129]. Reduced income further threatens food supply and the ability to pay for the education or health of other family members, resulting in the disruption of the entire social fabric of the family [128, 129]. AIDS-related stigma has an enormous negative impact on social relationships, access to care and psychological wellbeing leading to poor health outcomes [129]. Social interventions to support PLWHA are likely to be effective if they are based on holistic assessments and evidence-based intervention strategies with collaborative planning [130]. Such intervention strategies should focus on context-specific needs assessment and collaborative planning [130]. The interplay between the individual, family and social system needs to be recognised and care facilitated through effective communication and counselling.

1.3.5.4 Spiritual concerns of PLWHA

Spirituality is a sense of relationship to something greater than oneself, it is a person's relationship with a supernatural being, which could be known as God, Jesus Christ, Mohammed, Buddha or simply the Supreme Being [131]. PLWHA experience spiritual distress [17] throughout the disease trajectory however, spirituality can be positively or negatively experienced throughout the life course. As a study reported 45% of its participants had increased positive spirituality following HIV diagnosis [132]. Evidence also suggest that positive spirituality acted as a protective factor for physiological disease progression in PLWHA, compared to those whose spirituality decreased following HIV diagnosis [17]. Negative manifestations of spirituality include viewing HIV as a sin, anger at God and spiritual struggle, and are linked to poor adherence [133], which results in rapid disease progression [17, 132]. Consequently, PLWHAs' state of spirituality and practices could determine whether spirituality will be a protective or risk factor to HIV disease progression.

PLWHAs' spirituality predicts well-being and outcomes such as functional health status, improvements in life satisfaction and health-related quality of life when controlling for age and HIV symptoms [134]. Positive spirituality have been linked to less pain and increased physical function

[135], less psychological distress and depression [136-138], better cognitive and social functioning with fewer HIV symptoms, and better mental wellbeing [137, 139].

This burden of symptom and concerns (physical, psychological, social and spiritual) experienced by PLWHA demands a more concerted, holistic approach to care, and further academic study of its potential effect for PLWHA at the level of healthcare systems in countries such as Ghana.

1.3.6 Holistic care

Jan Smuts (a Prime Minister South African Republic and philosopher), coined the term 'holism' from which emerged 'holistic'. He described holism as a concept that the 'whole' is more than the sum of its systemic parts' [140]. It has been argued that the human being is made up of body, mind and spirit, which is unified into a whole, with inseparable parts. When there is harmony and balance within the parts it results in maximum wellbeing [141]. Although health can be defined as physical, social, emotional, cognitive and spiritual, a person is truly healthy when they experience wellbeing. Percival, who wrote the first textbook of medical ethics advocated for a holistic approach and noted: "the feeling and emotions of the patients require to be known and to be attended to, no less than the symptoms of their diseases." [142]. Huljev and Pandak defined holistic medicine as taking into account the complete person in terms of physical, psychological, social, and spiritual, in the management and prevention of disease [143]. These different states are equally important and ought to be managed together with the aim of treating the person as a whole. Using the holistic approach implies that HCP is aware of the patients' whole life situation [144].

The principles of a holistic approach includes: the patient is a person, not just a disease; proper therapeutic care requires a team approach; patient and HCP are partners in the treatment process; and treatment involves resolving the cause of the illness, not just managing symptoms [143]. It is crucial to know from a person-centred approach, how responding to the holistic needs promotes an individual's health and wellbeing. The concept of holistic health is about viewing a person's physical, social, emotional, and spiritual components as an integrated whole, resulting in a broader concept of care where a person's holistic needs are met in maximising health and wellbeing [145].

1.3.7 Person-centred approach as holistic care

Mezzich defined person-centred care as care 'dedicated to the promotion of health as a state of physical, mental, social, and spiritual wellbeing, as well as to the reduction of disease and founded on mutual respect for the dignity and responsibility of each individual person' [146]. The author asserts that contextualising care includes cultural diversity as well as spirituality [146]; and demonstrating respect for the person behind a serious illness is considered essential in motivating person-centred care [147]. Also, it is crucial for clinical care to engage patients in a thoughtful manner both as individuals and collectively, including those critical of healthcare, in order to restate the dialogic foundation of the medical profession [148]. These assertions appear to argue for a more inclusive, holistic, and person-centred perspective to enhance and strengthen the foundations of medical care [149]. Mezzich affirms to extend the focus of medicine to person and to better understand how the different elements of the person-centred approach influence the process and outcome of care, and to respectfully work in collaboration with patients to achieve their health and life's goals.

1.3.7.1 Concepts of person-centred care

The term 'person-centered care' is used throughout this thesis as opposed to 'patient-centred care', which has been used to describe similar concepts. 'Person-centred' is preferred due to its broader coverage of care settings and recognition of people as individuals beyond their status as 'patients' [150].

Various concepts of PCC have been described including that of the Institute of Medicine (IOM), which described PCC as 'Health care that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients' wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care' [34]. Eight concepts of PCC discussed in literature have been summarised in Table 3. Of these, three concepts have been widely used and are prominent in PCC research area: the Stewart [151], Stewart et al., [152] concept, the Mead and Bower [153] concept, and the Epstein et al., [154]. Some of the concepts have been developed with the aim of making the key components of PCC more applicable in practice. It should be noted that the main focus of the Epstein et al., [154] concept is patient-centred communication rather than a wider approach to PCC. Epstein et al.'s concept is deemed relevant due to its focus on patient-centred communication as the way to achieve patient-centeredness.

However, in considering a definition of PCC as a theory to underpin this study, it was important to choose a PCC concept that focuses on holistic care to be able to address the domains of need (physical, psychological, social and spiritual) experienced by PLWHA. Selman et al. noted the importance of holistic assessment to achieve PCC for PLWHA, noting that spiritual wellbeing receives less attention [155]. This is supported by McEvoy's concept analysis of Holistic practice [156].

Table 3: Concepts of PCC described in literature with specific components of delivery

Concepts of PCC	**Specific components**
Picker Institute [157].	▪ Access to care ▪ Respect for patients' values, preferences and expressed needs ▪ Information, communication and education ▪ Co-ordination and integration of care ▪ Emotional support and alleviation of fear and anxiety ▪ Involvement of family and friends ▪ Physical comfort and pain alleviation ▪ Transition and continuity.
Kitson et al. [158]	▪ patient participation and involvement, ▪ the relationship between the patient and the HCP, and ▪ the context where care is delivered.
Sidani and Fox [159]	▪ holistic care, ▪ collaborative care, and ▪ responsive care.
Mead and Bower [153]	▪ the biopsychosocial perspective ▪ the patient-as-person concept ▪ sharing power and responsibility ▪ therapeutic alliance ▪ doctor as person,
Stewart [151], Stewart et al. [152]	▪ exploring both the disease and the illness. ▪ understanding the person as a whole. ▪ finding common ground in three main areas: agreement between the doctor and the patient on the nature of the problem; the plan for treating or managing the problem; and the role of the patient ▪ incorporating prevention and health promotion ▪ enhancing the patient-doctor relationship ▪ the need to be realistic, both in teamwork and team building and in time.
Morgan and Yoder [160]	▪ holistic care, ▪ individualised care, ▪ respectful care, and ▪ empowering care.

Mezzich [146]	▪ physical, ▪ mental, ▪ social, and ▪ spiritual wellbeing, as well as to ▪ the reduction of disease and founded on mutual respect for the dignity and responsibility of each individual person'
Epstein et al., [154]	▪ offering patients opportunities to provide input and participate in their care ▪ enhancing partnership and understanding in the patient-doctor relationship ▪ considering patients' needs, wants, perspectives and individual experiences ▪ actions taken to achieve patient-centeredness philosophy including health systems innovations, technical interventions and interpersonal behaviors ▪ patient-centered communication including communication between HCPs, the patient and their family to enhance patient-centeredness.

Of these concepts of PCC described in Table 3, the concept of PCC chosen for this thesis is the one described by Mezzich as care 'dedicated to the promotion of health as a state of physical, mental, sociocultural, and spiritual well-being, as well as to the reduction of disease, and founded on mutual respect for the dignity and responsibility of each individual person' [146]. This description was chosen to reflect the domains of need experienced by PLWHA and the focus on holistic care delivery.

1.3.7.2 HIV/AIDS and person-centred care

Among the critical areas of action detailed for achieving the 90-90-90 targets is to keep individuals alive and healthy through the delivery of 'person-centred and holistic care' [161]. Person-centeredness is key to quality healthcare [162], and is represented in the statement 'nothing about me, without me' [163]. The World Health Organisation (WHO) has recognised person-centred care (PCC) as a means to achieve the 90-90-90 targets set [41] however, PCC is a Western-originated concept that is claimed to be potentially applicable universally, despite it not being tested in Africa [39, 164]. Evidence from high income countries for conditions other than HIV has shown that a shift to PCC enhances collaboration between healthcare providers and patients and adherence to treatment plans [165, 166], improves health outcomes, and increases patient satisfaction [167, 168]. Moreover, the adoption of person-centred approaches in primary

healthcare has resulted in significant benefits for patients, enabling better health management by being informed and supported [169]. This will be increasingly important as PLWHA age and live with complex comorbidity and clinical uncertainty.

PCC has been seen as a Western concept which appears to be accepted universally, and has not been explored in Africa [39] or in HIV-specific care. Person-centeredness is also context specific and may be interpreted and applied differently [39] therefore, there is the need to understand what PCC means universally and contextually.

1.3.8 Palliative care and person-centred care

Palliative care skills might be useful and appropriate to draw on for the delivery of PCC. Palliative care is known to deliver holistic and person-centred care for people facing serious illness like HIV/AIDS, with the goal of improving their quality of life through early identification, assessment and treatment of physical, psychosocial, emotional, and spiritual concerns [43]. Also, the WHO state that 'palliative care is an essential component of a comprehensive package of care for people living with HIV/AIDS because of the variety of symptoms they can experience' [170]. It has also been argued that the effectiveness of palliative care is limited when it failed to provide holistic care contributing to physical, social, spiritual, and emotional suffering [171]. Therefore, it made sense to use palliative care skills as an exemplar of person-centredness order to develop a PCC intervention for PLWHA.

1.3.9 Summary and rationale for the study

HIV/AIDS remains a disease of public health importance especially in the sub-Saharan region, although the infection rates have stabilised, access to ART is improving resulting in PLWHA living longer. Moreover, the social, psychological and economic impacts of HIV on PLWHA, their families and society, notably in resource-limited countries such as Ghana, is an indication for care and support approaches that could deliver holistic care for PLWHA. HIV/AIDS has become a chronic illness and therefore requires a holistic and person-centred care approach in order to meet the physical, social, psychological and spiritual needs of PLWHA.

Several studies including policy documents have been published on the benefits of person-centred care [172-174], which has therefore been pivotal to recent moves to enhance global HIV care and support [41-43]. However, person-centred care is a construct developed in the West it is not known what it means in Africa [39, 164], or in HIV care. Person-centeredness is context

specific and may be interpreted and applied differently [39] depending on the context. Consequently, the purpose of this study is to identify the existing models of person-centred care in community settings where PLWHA receive care and appraise their effectiveness in improving outcomes for PLWHA. This study further sought to use evidence from the existing person-centred care models being delivered in the community to explore and understand the meaning of person-centred care from the perspectives of PLWHA receiving care in community settings in Ghana. This information was used to inform a community-based person-centred intervention development and feasibility testing of this intervention to improve outcomes for PLWHA.

Chapter 2 Aim and Objectives

2.1 Aim

To develop a community-based enhanced care intervention to improve person-centred outcomes for people living with HIV/AIDS, and to test the "feasibility" of a cluster randomised controlled trial in terms of participant recruitment and retention, and intervention delivery.

2.2 Objectives

Objectives are presented under the headings of the MRC complex interventions guidance

(i) "*Identifying the evidence base*"

Objective 1. To conduct a systematic review identifying evidence for person-centred models of community HIV management, and their impact on outcomes for PLWHA.

(ii) "*Identifying/ developing appropriate theory*"

Objective 2. To explore the views of PLWHA and healthcare professionals (HCP) about current HIV/AIDS care, its accessibility, and to determine which person-centred outcomes matter to PLWHA.

Objective 3. To map the qualitative data from objective 2 onto the components of person-centred care theory to determine which components map and what extra components are required.

(iii) "*Modelling process and outcomes*"

Objective 4. To integrate findings from objectives 1-3, modelling the potential processes, outcomes, and mechanisms of action for the intervention.

Objective 5. To deliver and test the feasibility of a cluster randomised controlled trial of the intervention in terms of recruitment and retention, and to determine intervention delivery, estimate of potential effect and suitability of measures.

Chapter 3 Methods

3.1 Introduction

This chapter describes the design and methods for each phase of the study.

Phase 1: The first phase involved a systematic review which identified evidence for person-centred models of community HIV care and their impact on outcomes for PLWHA. This included identifying components of the person-centred models and describing the care structure, processes and outcomes of the models delivered using the Donabedian framework of healthcare quality [175], with appraisal of the quality of the evidence.

Phase 2: The second phase involved a qualitative interview study of HCP and PLWHA in Ghana. The semi-structured interviews explored the views of PLWHA and their HCP about current HIV/AIDS care, need for and accessibility of PCC, and determined which person-centred outcomes matter to PLWHA. Findings from this interview were mapped onto components of a person-centred theory in an expert intervention development workshop and informed contents of a proposed intervention. This led to the development of a conceptual model of person-centred care (PCC) and a framework that informed PCC delivery for PLWHA. This person-centred framework was modelled as a complex intervention (community-based enhanced care intervention (CECI)), having a logic model and PCC theory which underpinned CECI development and acted as the theory of change.

Phase 3: The third and final phase of this PhD tested the feasibility of delivering the CECI intervention in community settings for PLWHA in Ghana. Feasibility studies ask can a study be done, should you go ahead with it, and if so, how? [176]. The essential feature of feasibility studies is that they answer questions to inform a future definitive study [177] (see Figure 3 for the conceptual framework for feasibility studies). This phase of the study involved a mixed methods cluster randomised controlled feasibility trial, which comprised quantitative outcome data collection and a post-trial exit interviews with a purposive sample selected from trial participants. This was reported using the CONSORT extension for feasibility trials. The main uncertainties this feasibility trial addressed were participant recruitment and retention, HCP training on the intervention, intervention delivery and acceptability, and estimation of the potential effect size of the intervention.

This trial was registered with the ISRCTN registry with study ID ISRCTN13630241.

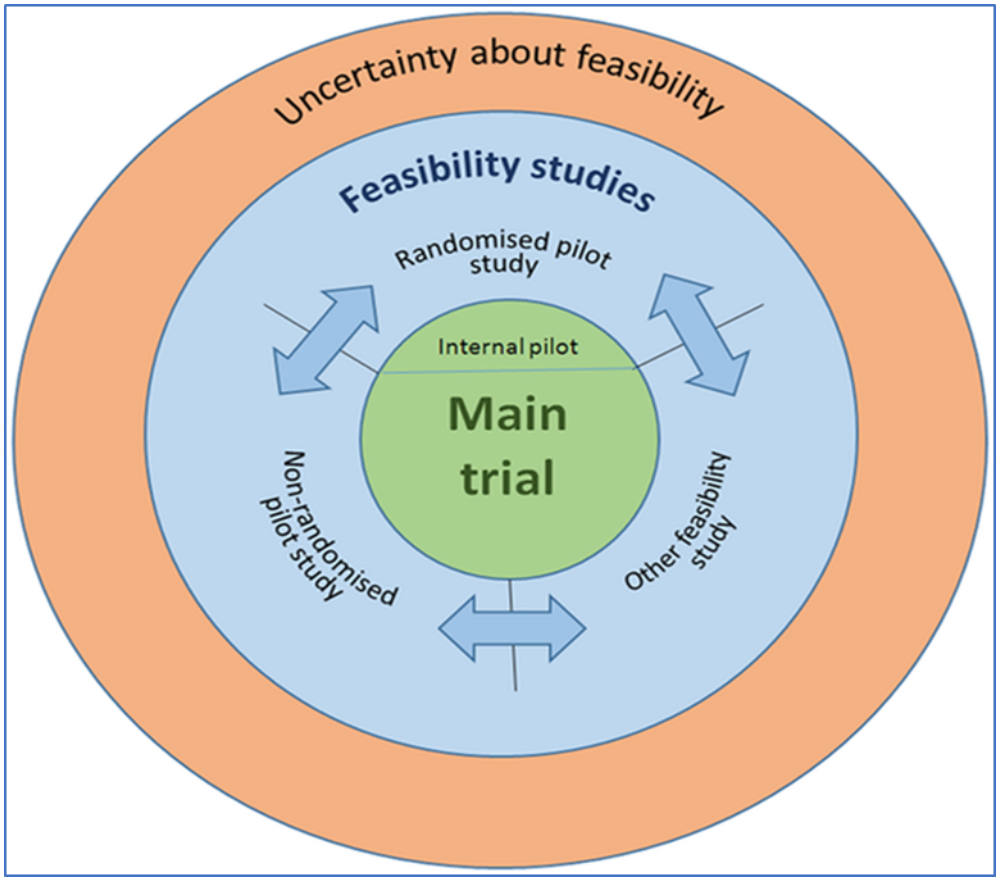


Figure 4: Conceptual framework for feasibility studies, adapted from Eldridge et al. [177]

3.2 Complex interventions

Complex interventions have traditionally been defined as “interventions with several interacting components” [178]. The MRC guidance described complex intervention as interventions which:

- are made up of number of interacting components;
- require number of behaviours by those delivering or receiving the intervention;
- aimed at number of groups including healthcare professionals and patients;
- involve number and variability of outcomes;
- allow for degree of flexibility or tailoring [176]

CECI is a complex intervention as it is made up of several components: training, supervision and mentoring HCP on CECI including holistic assessment tools and care plans; it involved groups of

PLWHA and HCP; and aimed to change the behaviour of both the HCP and PLWHA so that the symptoms and concerns of PLWHA are more holistically assessed and addressed.

In developing and evaluating complex interventions, there are a number of challenges that relate to ensuring fidelity in the design and delivery of the intervention [179, 180]; the influence of the contextual factors [181, 182]; the organisational and logistical issues in implementing an intervention in clinical practice and the identification of the mechanism of action of the intervention and the relationship to the outcomes [183]; as there can be long complication causal chains linking interventions with outcomes [183]. The aim of the MRC guidance is to assist researchers to adapt appropriate methods while recognising these challenges of developing and evaluating complex interventions. The MRC guidance advises that dealing with this complexity depends on the aims of the evaluation [178]. However, the intervention may be modified in an iterative manner as required once effectiveness has been established. Important questions to ask are: how does the intervention work, what are the vital constituents and how do the constituents fit together to exert their effect (mechanism of action)? [178, 184].

The MRC guidance advises that: “best practice is to develop interventions systematically, using the best available evidence and appropriate theory, then to test them using a carefully phased approach, starting with a series of pilot studies targeted at each key uncertainty in the design, and moving on to an exploratory and then a definitive evaluation” [178]. In the present study the CECI was developed following a systematic approach recommended by the MRC guidance, using the evidence obtained from a systematic review, qualitative interviews to inform intervention development with PLWHA and HCP, and utilising the theory of person-centred care. In line with the MRC guidance, feasibility of the CECI must be tested to determine whether and how it can be optimised and delivered within multiple community HIV care settings with anticipated heterogeneity in skills, practice and HCP composition.

3.3 The MRC guidance

The MRC framework for developing and evaluating complex interventions was initially developed and published in 2000 [185]. However, several limitations were identified with this initial framework [176], which prompted recommendations for a greater attention to be paid to early phase development and piloting work [186]; a less linear but more flexible model of development and process evaluation [187]; integration of process and outcome evaluation [188], recognising

that complex interventions tailored to local contexts rather than completely standardised could work best [187], and making greater use of insights provided by theory of complex adaptive systems [189]. The initial MRC linear framework was updated and published in 2008, with a model that allows for movement between each stage in the development and evaluation of complex interventions [178].

The MRC guidance has four research stages: Development, Feasibility and Piloting, Evaluation and Implementation (see Figure 5). The MRC guidance [178] emphases the importance of the **development stage** of an intervention, which involves thee components. The first, '*Identify the evidence base'* including conducting a systematic review to establish what is known about similar interventions. The second is '*Identifying/ developing theory'* the guidance advises the importance of developing a theoretical understanding of how the intervention may possibly change process by identifying and appreciating existing evidence and theory. Nevertheless, if this evidence is not available, new research ought to be conducted with stakeholders. By integrating existing and new evidence, a deeper understanding of the theoretical model of how the complex intervention may work is then attained [178]. Finally, in the *Modelling process and outcomes,* the understandings and insights from the theory phase are applied to develop the intervention and gain an understanding into how the intervention may affect the relationship between intervention and outcome [178].

The **feasibility and piloting stage** includes *Testing procedure* (including testing methods for their acceptability and feasibility), estimating the likely rates of *recruitment and retention* of participants and the *determination of appropriate sample sizes* for the evaluation studies [178]. The Feasibility and Piloting stage should aim to address all the uncertainties identified in the Development stage. The MRC guidance stresses the importance of this stage. This stage may be repeated multiple times (iteration between development and feasibility stages as required) before moving on to the formal evaluation of the complex intervention in the Evaluation stage [178]. The MRC guidance advises researchers to choose study designs that are suitable to the intervention paying attention to the choice of outcomes. In addition, the guidance recommends the use of appropriate qualitative and quantitative methods.

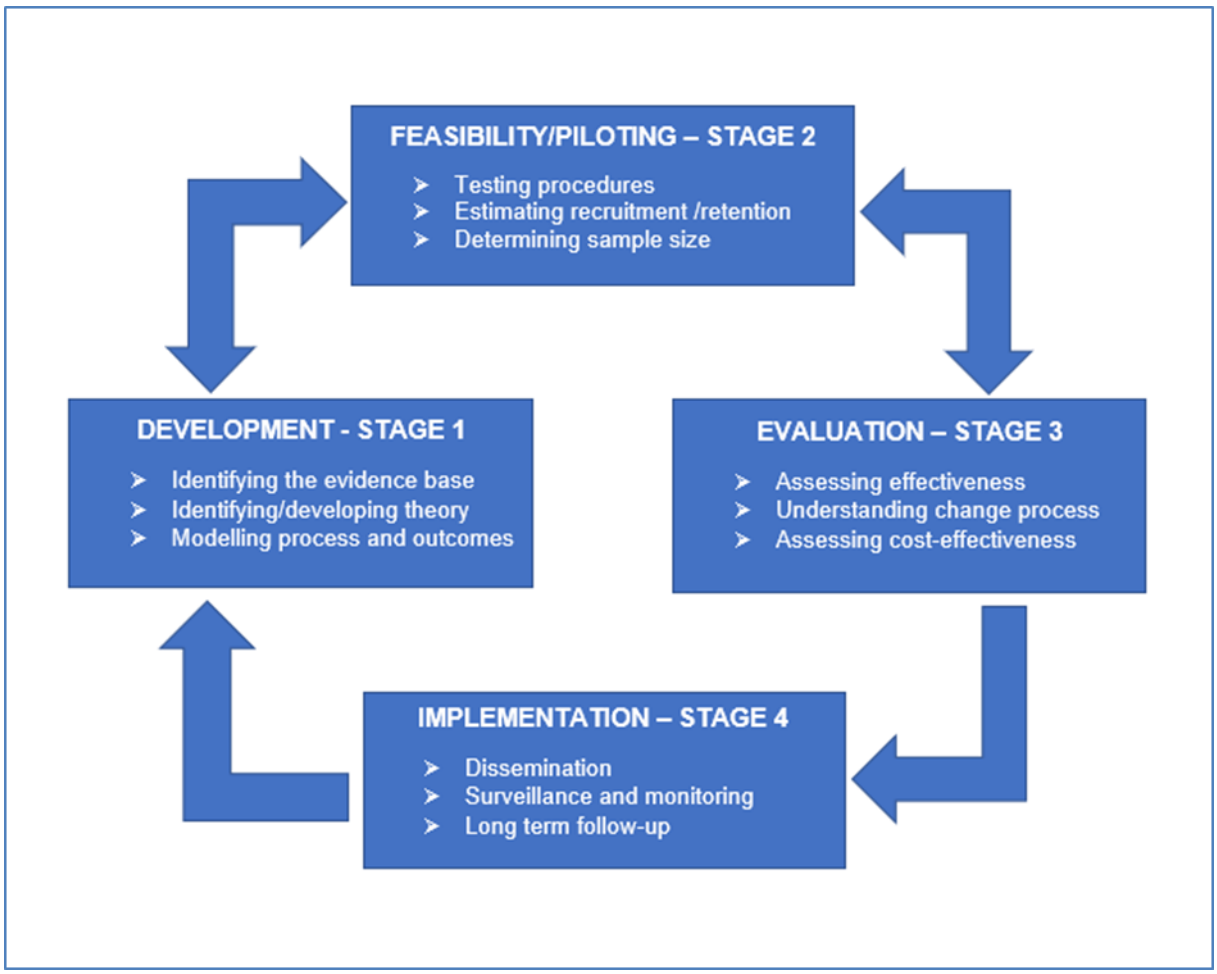


Figure 5: The four research stages of the MRC guidance adapted from Craig et al. [176]

In developing and feasibility testing of CECI for this thesis, the *Development and Feasibility stages* of the MRC guidance was used. This involved the development of CECI followed by the feasibility testing of CECI. The findings from the feasibility study will be used to inform a future definitive study as appropriate. The stages of the MRC guidance used in developing and feasibility testing of CECI is shown in Figure 6.

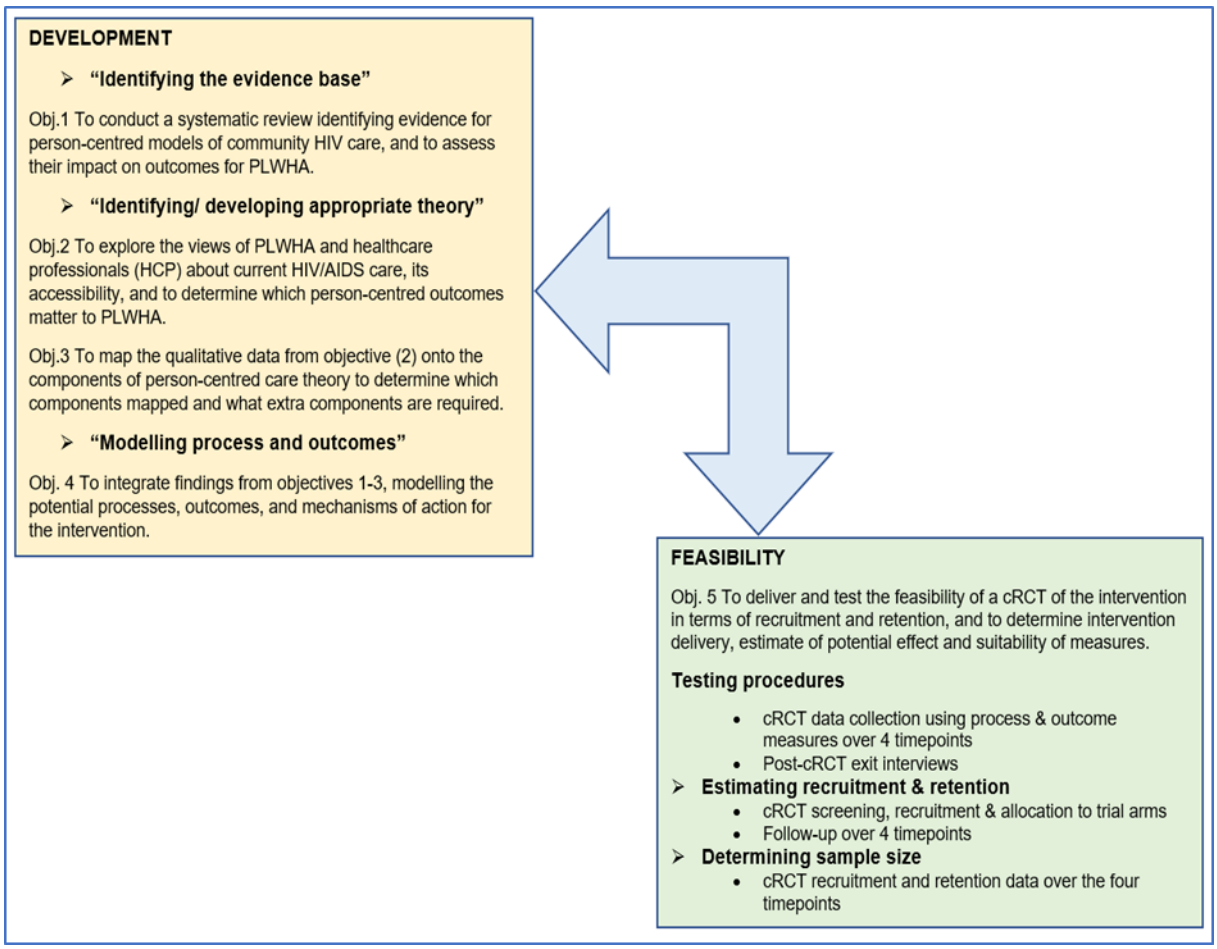


Figure 6: The Development and Feasibility stages of the MRC guidance mapped onto study objectives

3.4 Mixed methods approach (pragmatism)

The pragmatist views nature as 'existential reality' and knowledge as one that is useful and created through a line of action [190, 191]. It is therefore argued that, pragmatism presents an alternative approach to research philosophy that requires strict adherence to what underpins ontology and epistemology [192]. Ontology (assumptions about the nature of reality) and epistemology (the acceptable knowledge in the area of research) are the philosophical stances of researchers which affect their research paradigm [193]. Therefore, understanding epistemology and ontology depends on the research question or problem under investigation [190, 194, 195].

3.4.1 Rationale for using mixed methods design

A number of factors guide the choice of research methods, which includes: (a) the aims and objectives of the research; (b) ontological perspectives being adopted for the research [196]; (c)

epistemological perspectives of the research [197]; and (d) environmental and socio-economic characteristics of research participants, resources available, and the researcher [198].

The mixed methods design implemented in this PhD is consistent with the MRC guidance [199, 200]. Moore et al. [199] propose the use of qualitative study across various stages. For instance, in the early phases of evaluation,

> "…a vitally important early task is to develop a theoretical understanding of the likely process of change, by drawing on existing evidence and theory, supplemented if necessary, by new primary research, for example interviews with stakeholders" (p.9).

The author again emphasised the importance of drawing together different research methods at the feasibility stage,

> "…a mixture of qualitative and quantitative methods is likely to be needed, for example to understand barriers to participation and to estimate response rates" (p.10).

Therefore, the research objectives for this PhD were developed using the MRC guidance, specifically the components listed in the 'development' and 'feasibility' stages. It was observed that different methodological approaches were required in order to address these research objectives, necessitating a mixed methods design [201, 202]. Greene argued that "the greatest potential of mixed methods inquiry is the generative possibilities that accompany the mixing of different ways of knowing, perceiving and understanding" [203]. The use of mixed methods approaches also bring different benefits, that together can provide greater depth and breadth of inference than a mono-method approach, and on the basis that each method functions as a tool that is calibrated to answer specific research questions.

3.4.2 Application of mixed methods design using the MRC guidance

In the development stage of the MRC guidance, the researcher conducted a systematic review together with the adaptation of a person-centred care theory to underpin the intervention development. This then led to a qualitative exploratory phase that explored the views of PLWHA and HCP on current HIV care, how it is delivered and what constitutes person-centred care for PLWHA in more depth, which has been advocated to identify the causal processes and contextual factors that could be measured in testing the premise generated [204]. By integrating the existing

evidence and the underpinning theory with new evidence from stakeholders, a deeper understanding of the theoretical model of how the intended intervention may work was then attained in the development stage. In the modelling theory or processes stage, the understandings and insights from the theory phase were applied to develop the intervention and an understanding was gained of how the intervention could affect the relationship between intervention and outcome [178]. Testing the feasibility of the intervention in a cRCT to estimate recruitment and retention, and the potential effect of the intervention necessitates a quantitative approach; and in order to explain the quantitative results from the cRCT, a final post-cRCT qualitative interviews were conducted. Therefore, the feasibility testing phase of this PhD was implemented as a sequential explanatory design [202, 205].

3.4.3 Sequential explanatory design

Sequential designs involve multiple stages of data collection where the research aim and questions determine the specific sequence [206], to enable each stage of the study to shape subsequent stages. This study used a sequential explanatory design with the embedded qualitative data in the feasibility testing phase. The qualitative data was used to explain or elaborate on the quantitative results obtained during the cRCT [207]. This method involved two phases: (a) quantitative outcome data collection and analysis, and (b) post-trial exit qualitative interviews which were used to explain the results from the quantitative data collected earlier [202, 208, 209]. Additionally, an important consideration in sequential mixed methods design is the weight given to the data elements within the study in determining the theoretical drive of the study [210]. It has been suggested that in exploratory designs weight is usually placed on the qualitative element of the study, while explanatory designs usually place weight on the quantitative element of the study, although this is not always the case [206]. This feasibility cRCT placed equal weight on both elements implemented. The quantitative data collection utilised standardised measurement scales which brought potential strengths of quantification of results. The incorporation of a post-cRCT qualitative stage allowed for the exploration of the potential mechanism of action of the intervention, its feasibility and acceptability in addition to its use in clinical practice. This qualitative data also helped to explain the quantitative findings, which provided valuable insights which could be used to inform a future definitive study.

The combination of all these methods focused on the development and feasibility testing of this complex intervention and increasing the understanding of outcomes in order to improve the intervention. The mixing of the different methods involved in addressing the research aim has been described by each study objective and incorporated in the stages of the MRC guidance used for this study in figure 7. Details of the various methods used have been described by objectives in subsequent sections. Furthermore, the decision to use a particular data collection tool, be it a semi-structured interview or structured questionnaire, did not align to a specific ontological or epistemological viewpoint [211, 212].

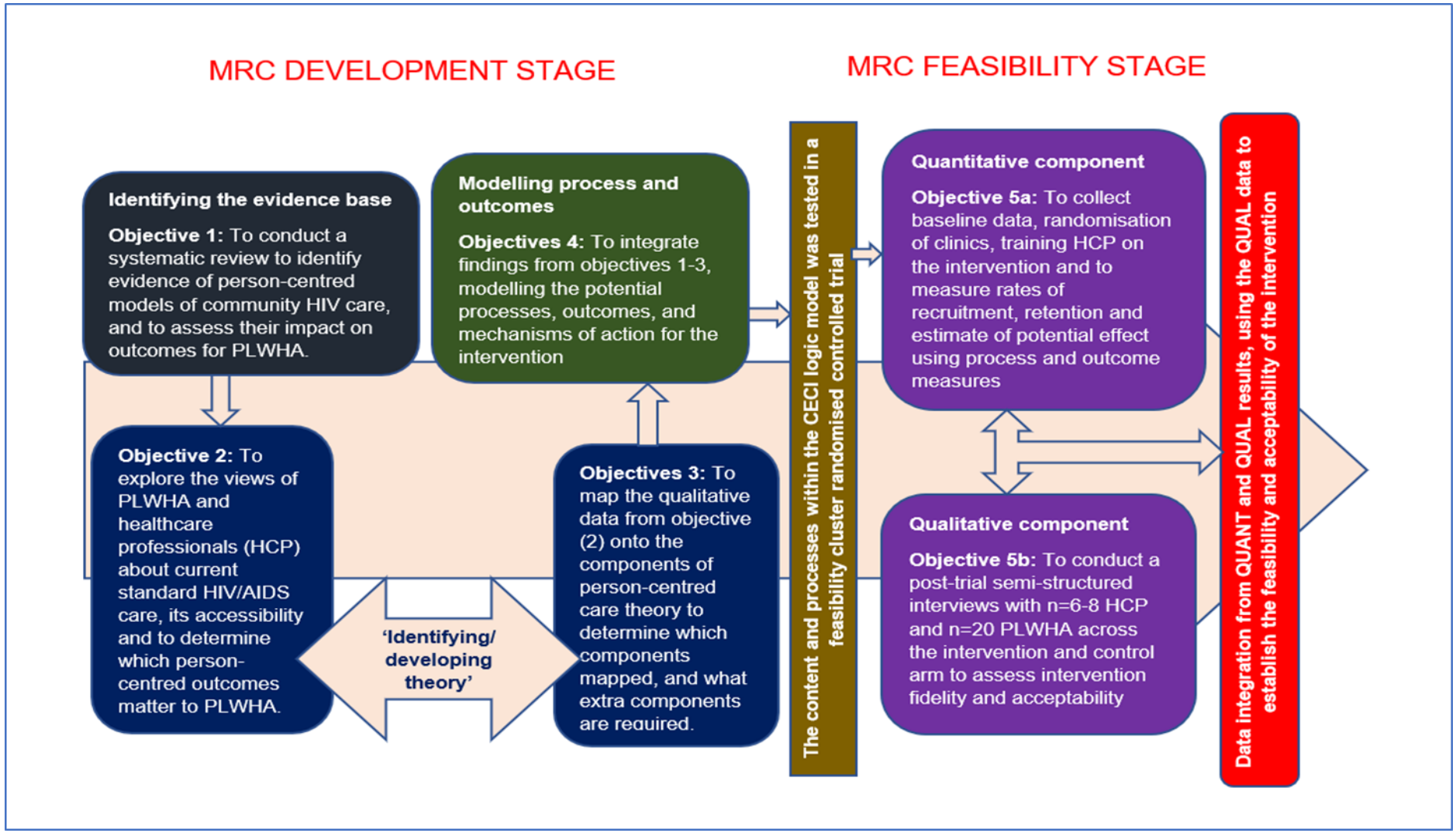


Figure 7: Study overview with thesis objectives incorporated within the development and feasibility stages of the MRC guidance

3.5 The MRC guidance and the underpinning theoretical model

3.5.1 The Theory of Change

A theory-driven approach has been proposed for the design and evaluation of complex interventions by the adaptation and integration of programmatic design and evaluation tool, Theory of Change (ToC), into the MRC guidance for complex interventions [213]. The ToC is a discussion-based process which is intended to generate a 'description of a sequence of events that is expected to lead to a particular desired outcome' [214, 215]. This description is usually captured in a diagram with narratives to provide a guiding framework for the study team and stakeholders. ToC is also a practical outline describing how the intervention affects change and could be reinforced by embedding behavioural change theories at critical points in explaining why particular links happen. The ToC has been proven to strengthen research in many different aspects including the development of the intervention, its feasibility and piloting, evaluation, and finally implementation (Figure 8) [213]. The ToC was employed throughout this study, strengthening the development and feasibility stages (highlighted by red dots in Figure 8).

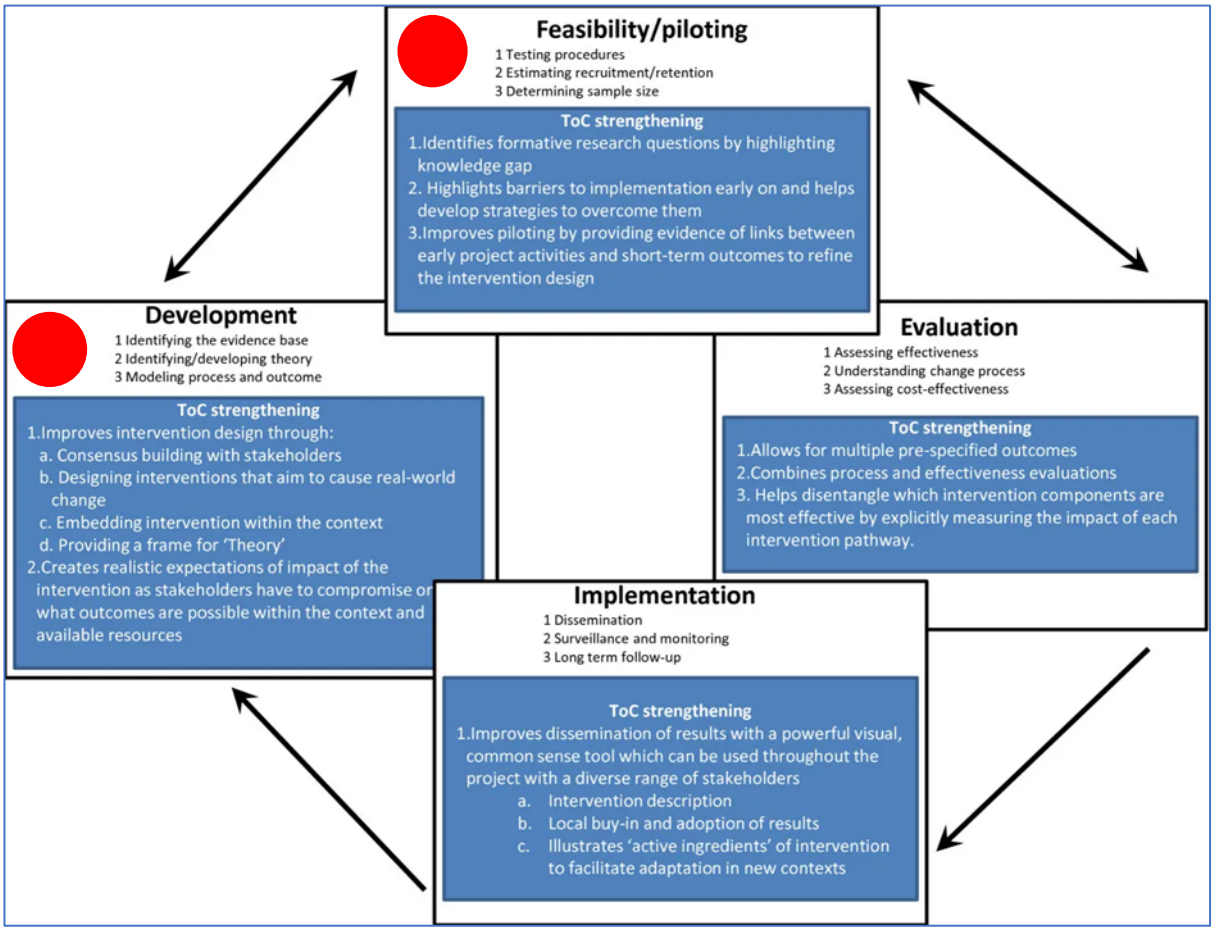


Figure 8: The integration of Theory of change into the MRC guidance for complex interventions, adapted from De Silva et al. [213]

3.5.2 Adapting Person-centred care theory as the ToC

The theory embedded to strengthen the ToC for this intervention is the theory of person-centred care (PCC) which is care 'dedicated to the promotion of health as a state of physical, mental, sociocultural, and spiritual well-being, as well as to the reduction of disease, and founded on mutual respect for the dignity and responsibility of each individual person' [216]. ToC explained the causal assumption and mechanism of action by which the intervention components worked to bring about change. The MRC guidance also highlights the importance of building a 'cumulative understanding of causal mechanisms' with the aim of learning from evaluations in order to 'design more effective interventions and apply them appropriately across group and setting' [178]. Therefore, using theory to underpin an intervention development is a crucial starting point, while the use of evaluations in testing and refining these theories are important to maximise its contribution to a wider evidence-base [217]. The aim of this PhD is to develop a complex

intervention to improve person-centred outcomes for PLWHA. Theories of change predict and explain how the interactions between the person living with HIV, the intervention components and how they are delivered may influence modifiable factors.

3.5.2.1 PCC as the ToC strengthened the development stage of the MRC guidance by

i. Improving the intervention design in relation to:
    - Building consensus with HCP and PLWHA in a qualitative interview
    - Designing the intervention with the goal of causing change in the way HCP delivered care and how PLWHA experienced that care
    - How the intervention was embedded within the local context
    - Providing a frame for 'theory'

ii. Creating realistic prospects of impact of the intervention as stakeholders concede on what outcomes are feasible within the context and available resources

3.5.2.2 PCC as the ToC strengthened the feasibility stage of the MRC guidance by

i. Identifying formative research questions which underscored the knowledge gap

ii. Highlighting barriers to the implementation of the intervention at the beginning and helped to develop strategies to overcome them

iii. Improving piloting by providing evidence of links between the development stage activities and short-term outcomes to refine the intervention design.

3.6 Setting, translations and ethics as applied to the whole study

3.6.1 Setting

The WHO's "Global strategy on integrated people-centred health services 2016-2026", has called for the reorientation of care models that prioritise primary and community care services, and delivers holistic and comprehensive care that is sensitive to the needs of individuals [26]. Currently, approximately 95% of HIV/AIDS care delivery is hospital-based. Consequently, one of the fast-track strategies to achieve the 90-90-90 targets, is to increase access to HIV/AIDS care by delivering 30% of services in community settings to improve retention in care [48]. UNAIDS has also emphasised the importance of community-wide systems in motivating the use of HIV care services and argues for research to be expanded in this area [218, 219]. Given that most PLWHA in Ghana have financial challenges that prevent them from accessing services delivered in hospitals that required substantive amount of traveling time [220], the researcher conducted this study in existing community settings where HIV care is delivered in order to reduce financial burden of having to travel long distances to access services.

The researcher therefore contacted HIV service providers in Ghana via telephone who helped in the identification of existing community-based HIV services to undertake this study. The researcher was referred to the West African AIDS Foundation (WAAF). The WAAF was contacted also via telephone, through the clinic lead, and the purpose of this study was explained to the clinic. The clinic was supportive of the study and agreed for their facility to be used as one of the study sites. The clinic lead was made aware earlier on during the discussion about the study, that two sites were required for the implementation of the whole study. Therefore, the clinic lead at WAAF suggested the Legon HIV clinic as a potential second site (as they both provide similar services). This potential clinic was also contacted via telephone about the study and the possibility of becoming the second site for study implementation (the telephone contact approach was used to identify the two study sites as the researcher was based in King's College London (KCL) when this initial liaison work was done). The clinic lead at the Legon clinic was also happy to partner with WAAF to implement this study so long as the researcher had ethics approval to start the study.

To have the study accepted at these two sites located in the Greater Accra Region of Ghana was advantageous as all the components of this study were conducted by the researcher, and it would have been difficult to complete this study within the allocated time if the study sites were located in different regions. Therefore, these two community clinics were chosen in Ghana to implement the whole study (both the intervention development and feasibility testing) as they both provide similar HIV care and support services, which is very crucial for the feasibility testing, ensuring that no clinic had an undue advantage over the other. Both clinics also have trained professionals who could be further trained to deliver the intervention.

3.6.1.1 Participating sites

West African AIDS Foundation (WAAF) is a registered Non-Governmental Organization (NGO) situated in Haatso, a suburb of Accra. WAAF is situated about 17 kilometres east of the city centre in the Ga East district of the Greater Accra Region of Ghana. WAAF currently provide care to a cohort of 750 PLWHA, with an average of 15 to 40 PLWHA seen on daily basis as outpatients only and the caseload are shared among HCP.

The Legon clinic is attached to the University of Ghana and is therefore managed by the University. Legon, a suburb of Accra, is situated about 12 kilometres north-east of the city centre in the Ayawaso district in the Greater Accra Region of Ghana. The Legon clinic provides care to a cohort of 500 PLWHA with an average of 10 to 30 PLWHA seen daily.

Both clinics have a primary mission to prevent the spread of HIV/AIDS and to mitigate its effects on communities by establishing care and support centres, in addition to developing and implementing pragmatic intervention programs. They also serve a geographical area characterised by a mixture of low, middle and high socioeconomic income statuses. Table 4 and Figure 9 has shown the details of services provided by the two clinics used in this study and their specific locations in terms of drive time distance respectively.

Table 4: Characteristics of study sites

Variables	Control site	Intervention site
PLWHA cohort	500	750
Average number of PLWHA seen per day	10-30	15-40
Accept National Health Insurance Scheme	Yes	Yes
Clinic days	Wednesday & Fridays	Monday to Saturday
Walk in services	Yes	Yes
Services provided	Care and treatment covering Tuberculosis Hepatitis, Prevention of Mother to Child Transmission, ART, pre-counselling and testing and sexually transmitted infection services	Care and treatment covering Tuberculosis Hepatitis, Prevention of Mother to Child Transmission, ART, pre-counselling and testing and sexually transmitted infection services
No. of doctors	4	2
No of nurses	4	4
Social workers	2	1
Laboratory services	Yes	Yes
Counsellors	2	2
Models of Hope (PLWHA trained to provide counselling and support to peers)	2	1
Healthcare assistance	2	2
Staff from Ghana AIDS Commission	1	2
See key population (lesbians, men who have sex with men (MSM), bisexual, sex workers and drug users)	Yes	Yes
Pastoral services	Occasionally	Occasionally
Psychological care	Occasionally	Occasionally

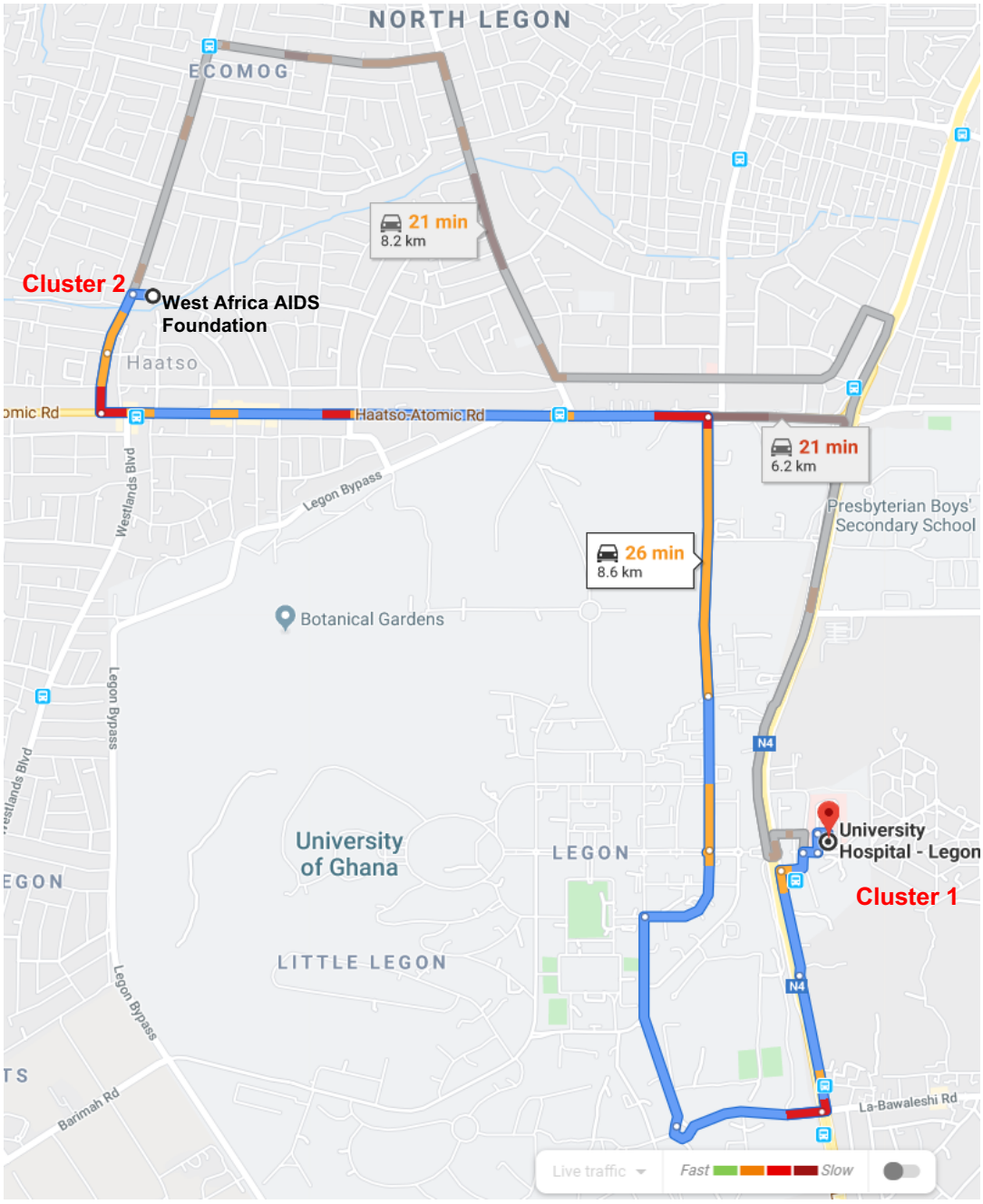


Figure 9: Location of study settings showing drive time distance between the two clusters

3.6.2 Translations

3.6.2.1 Study information sheets, consent forms and topic guide for Phase 2

All information sheets, consent forms and interview topic guides used in study Phase 2, were forward and backward translated into Twi (Twi is one of the local languages spoken in Ghana; the population for this study speak both English and/ or Twi fluently; hence the need for this

translation), by two independent translators: two each for both forward and backward translations. The researcher is also fluent in both English and Twi. This translation was done to increase the validity of study documents, recognising the potential loss of data quality when translation is inaccurate [221]. Also, the researcher recognised the many procedures and recommendations for the translation of study documents and the challenges of failing to ensure good translation [222, 223].

Moreover, although these translations were done, it was more difficult for most study participants to read the Twi language than the English language. As a result, most participants preferred the English version of the documents as they described them as 'easy to read and understand'. Participants also explained that although they could speak Twi fluently, they could not read nor write Twi, hence their preference for the English version (English is the official language of Ghana, therefore almost everyone in Ghana speaks English).

3.6.2.2 Translation of study documents for Phase 3

For study Phase 3, Although some study documents and data collection instruments were translated, they were not used due to the observation and explanations given by study participants regarding their literacy skills in Twi during the implementation of study Phase 2. As indicated in **section 3.6.2.1**, the study participants preferred the English version of the study documents, despite being fluent in both English and Twi.

3.6.2.3 Verification of interview transcripts against audio-recordings

In conducting interviews in Phases 2 and 3 of this PhD, study participants had the options of having their interviews in Twi, English or a combination of languages. Therefore, interviews that were conducted in Twi only or a combination of both languages were transcribed verbatim from Twi to English by the researcher who speak both languages. This category of transcripts in addition to the recorded versions were sent to an official Twi to English translator who verified the transcripts against the audio recordings for consistency, coherence and to ensure that no data was lost as a result of this translation.

3.6.3 Ethics

3.6.3.1 Ethics approval

The qualitative development study in the Phase 2 of this PhD was approved by the King's College London (KCL) Research Ethics Committee Reference no. LRS-16/17-4507 (APPENDIX A). Site specific approval was also received from the Ghana Health Service Ethics Review Committee (GHS-ERC) Reference no. GHS-ERC16/06/17 (APPENDIX B); and the Noguchi Memorial Institute for Medical Research - Institutional Review Board (NMIMR-IRB) Reference no. NMIMR-IRB004/17-18 (APPENDIX C). Approval for the Phase 3 of this PhD - the mixed methods feasibility cRCT was granted by the King's College London Research Ethics Committee (LRS-17/18-7216) (APPENDIX D), and the site specific approval was again granted by the Ghana Health Service Ethics Review Committee (GHS-ERC) GHS-ERC008/06/18 (APPENDIX E) and the Noguchi Memorial Institute for Medical Research Institutional Review Board (NMIMR-IRB) NMIMR-IRB004/17-18 amend. 2018 (APPENDIX F).

3.6.3.2 Ethical considerations

Conducting research among participants with chronic conditions such as HIV/AIDS raises several ethical issues. PLWHA experience physical, psychological, social and spiritual symptoms and concerns [5, 102-104], consequently these group of participants are considered vulnerable and require special attention in relation to research [224]. Therefore, the following ethical issues were considered when designing and conducting this study.

3.6.3.2.1 Informed consent

PLWHA at every stage of life deserve the best possible care, as has been the goal of UNAIDS and WHO [27, 48]. Informed consent in this study involved four components: providing study information to potential participants, the potential participants' understanding of this information to make an informed decision, the participants' not being coerced to partake in the study, and the participants giving formal consent in the form of signing a consent form [225-228]. The researcher obtained informed consent by giving full information about the study to potential participants ensuring that the participant understood this information and had cognitive ability to make a decision and voluntarily consented to take part in the study [225,

229, 230]. Therefore, in conducting this study, informed consent process included all the interactions that occurred during the research process which informed the participant about the study in addition to receiving information on the study and signing the consent form. This was done to respect participants' autonomy and to protect their welfare [231].

3.6.3.2.2 Privacy and confidentiality

Privacy and confidentiality involves the avoidance of any issue of covert research, which violates participants' privacy [193, 232]. The researcher assured study participants of protecting their privacy regarding any disclosure they made during the study. However, prior to the interview it was explained that any disclosure that is considered harmful and put participants or others' safety at risk, would need to be discussed with the appropriate authorities. Participants were assured that disclosure of such information will be done to protect their safety and not to violate their right to privacy.

3.6.3.2.3 The principle of beneficence

The principle of beneficence stipulates that the researcher strategised to minimise harm but maximise benefits [233, 234]. There are two aspects to the principle of beneficence (a) a right to freedom from harm and discomfort for participants and (b) a right to protection from exploitation [235]. Before seeking ethical approval to conduct this study, the researcher had considered the potential risks and benefits of this study to participants. The risk of harm was low as this study did not involve any invasive procedures, hence there was no physical harm; however, there was a possibility that psychological harm, loss of privacy, emotional distress or embarrassment may have occurred as a result of being involved in the study. Possible benefits included accessing a potentially valuable intervention and increased understanding of HIV disease [235]. These potential risks and benefits were explicitly stated in the written informed consent documents used in this study. The researcher also implemented a distress protocol to minimize all forms of distress and harm in aligning with the principle of beneficence. Participants were also protected from any form of exploitation by keeping in confidence any information provided or disclosed by participants involved in the study, and not to use any shared information against the participants.

3.6.3.2.4 The principle of justice

The principle of justice relates to treating study participants fairly and protecting their right to privacy. This study used an inclusion and exclusion criteria, which was approved by the ethics committees involved in this study to guide the selection of participants who have the experience to contribute to the purpose of the study, ensuring that no participant was excluded unduly. Fair treatment of participants also relates to fairly treating actual or potential participants who declined participating in the study without any partiality [236]. In this study, participants were made aware through the information and informed consent documents that they had the right to decline participation or withdraw from the study at any time without any explanation to the researcher and doing so did not affect the care they receive.

Participant's choice regarding HIV/AIDS status disclosure to family or friends were respected. This was crucial to protect their rights to privacy and confidentiality [237] due to the level of stigma associated with such disclosures. The researcher also managed all data in line with data protection legislation to protect participants' rights to anonymity or confidentiality. Confidentiality also required the anonymisation of research participants' identity [194], therefore the identity of PLWHA and HCP who took part in this study were anonymised and their data treated with strictest confidence, ensuring that no identity was disclosed throughout the research process. Study participants' names were replaced with identification codes or pseudonyms [194], making it impossible to link their data to them. Participants' consent documents which contain identifying data were kept locked in a separate cabinet from other data collected and these cabinets are only accessible to the members of the research team.

3.6.3.2.5 The question of equipoise

The question of equipoise was also taken into consideration, which refers to sincere uncertainty that intervention delivered in one arm of a trial is superior over that delivered in the other arm of the trial [238, 239]. It was not known whether the enhanced care intervention was going to have any potential effect in HIV population as it was not part of routine care and had not previously been evaluated.

3.7 Data management and storage

A digitally encrypted audio-recorder with password protection was used to record all interviews and data were uploaded to the password protected secured server hosted by KCL, and subsequently delated from the digital recorder. Recorded interviews were transcribed verbatim and pseudonymised during transcription. Personal identifiable data from interview transcripts relating to names, clinics and geographic locations were removed during transcription and participants' IDs were used in all the quotes from qualitative data in order to protect their anonymity. Transcripts were checked for accuracy before they were uploaded to NVivo version 11 (for intervention development interviews) and version 12 (for feasibility post-trial interviews) for analysis. Using this qualitative data management software helped to manage the volume of data collected.

Baseline and follow-up data were entered as soon as possible after collection into an SPSS version 25 database. Although ideally a double data entry is recommended [240], not all data were double entered, due to limited time and resources. However, all data from ten randomly selected participants were double-entered and cross-checked to identify any systematic errors in the data entry processes, for which none were found. Two of the outcome measures (APCA POS and MOS-HIV) had some items reversed and recoded after data entry. There is a total of 7 items on the APCA POS patient version, of this, 4 items were reversed and recoded. Likewise, the MOS-HIV has a total of 35 items of which 11 items were reversed and recoded.

Data collected were stored in accordance with the Data Protection Act (DPA) 2012 [241] of Ghana and the General Data Protection Regulation 2018 of the United Kingdom [242] (the researcher completed the associated KCL online GDPR training in May 2018). In order to ensure anonymity of data, all participants were assigned unique ID numbers, which was used on all study related documents except for the consent forms. Consent forms and participants list of ID numbers and names were stored separately from the study data. All digitally recorded interview files were stored with password protection on a secured server at KCL and, backed up on the department server for security and on an encrypted and password protected USB stick, which is locked in the filling cupboard at the study site. All soft copy of data and audio recordings were encrypted, and password protected, and all hard copies were kept in locked

cabinets at the clinic. Participant packs for recording the quantitative data, were stored in a locked filing cabinet throughout the data collection period and were stored in the office of the clinic lead after data collection and entry was completed.

Stored data will be accessed by the research team for up to 3 years in accordance with the DPA 2012 [241] and GDPR 2018 [242]. After this period, all data will be permanently deleted or destroyed, as Creswell [237] argued that it is important to keep data for a reasonable period, after which it can be destroyed. This research is the academic property of King's College London and the researcher hence, findings will be used mainly for this PhD and other potential academic publications, and all relevant information or data will be held by the researcher.

3.8 Phase 1: Thesis objective 1

(MRC Development stage: "Identifying the evidence base")

To conduct a systematic review identifying evidence for person-centred models of community HIV management, and to assess their impact on outcomes for PLWHA.

Review questions in relation to thesis objective 1:

What are the structures, components, processes and outcomes of person-centred care delivered in community settings using the Donabedian framework of healthcare quality?

Are patient outcomes improved by models of community HIV management which aim to be person-centred?

What is the quality of the evidence?

3.8.1 Design

A systematic literature review was carried out in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [243]. This review was conducted to identify the evidence for person-centred models of community HIV management and their impact on outcomes for PLWHA, and to use this evidence to guide a person-centred intervention development for PLWHA. This is also consistent with the MRC guidance for developing and evaluating complex interventions. The quality of studies included were measured using the Standard Quality Criteria for Evaluating Primary Research papers [244].

3.8.2 Definition of terms

Person-centred care (PCC) - Mezzich defined PCC as care 'dedicated to the promotion of health as a state of physical, mental, sociocultural, and spiritual well-being, as well as to the reduction of disease, and founded on mutual respect for the dignity and responsibility of each individual person' [146]. This definition was chosen because, evidence suggest that PLWHA

often experience distressing physical, psychological, social and spiritual symptoms and concerns which impact on their quality of life [5, 102, 104]. Considering this definition of PCC, the focus of this systematic review was to identify which components of PCC are being delivered in community settings as published in the peer review literature. This review therefore considered models of care that are described as person-centred and address person-centred components including physical, psychological, social and spiritual wellbeing among PLWHA, alongside HIV disease management [143, 146, 155, 245].

Community-based health services (CBHS) as defined by WHO, include outreach services, primary or community or mobile clinics, home visit and home-based care services either delivered or led by formally trained HCP [76]. The rationale for choosing only those services delivered or led by HCP is that, trained professionals are required to assess, plan and manage HIV care including giving appropriate medications, referrals, and delivering PCC as part of disease management.

For the purposes of this review, adults are persons from age 15 years or older [246].

3.8.3 Search strategy

Relevant studies were identified by searching electronic databases: CINAHL, Embase, PubMed, Medline, PsycINFO and Web of Science. We hand searched reference lists of included studies to identify additional studies. Studies spanning from 1980 (HIV was first diagnosed in the 80s) to February 2017 (updated in April 2019 and January 2020 respectively) were included.

The search strategy combined the keywords ‘HIV’ OR ‘AIDS’ AND ‘person-centred care’ OR ‘patient centred care’ OR ‘holistic care’ AND ‘community care’ OR ‘primary care’ OR ‘home-based care’ AND ‘interventions’ OR ‘implementation’ OR ‘evaluation’ OR ‘effectiveness’. Multiple keyword sets were used to broaden the search and increased sensitivity to the databases. A piloting of the references generated by this strategy is given in Table 5 below.

Table 5: Preliminary literature search using the search strategy

Database	Search terms/ Subject Headings	Number of hits*
EMBASE (Ovid)	1. HIV or Human Immunodeficiency Virus	381939
	2. AIDS or Acquired Immune Deficiency Syndrome	209389
	3. HIV and AIDS	91394
	4. HIV*	381750
	5. AIDS*	185363
	6. HIV* and AIDS*	91904
	7. 1 or 2 or 3 or 4 or 5 or 6	491921
	8. Person-centred care	64419
	9. Patient-centred care	65362
	10. Client-centred care	755446
	11. Family-centred care	64144
	12. Personalised care	755621
	13. Individualised care	755703
	14. Holistic care	4325
	15. Holistic assessment	505
	16. 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15	759573
	17. Community care	121703
	18. Community-based are	120135
	19. Community and home-based care	391
	20. Home-based care	71604
	21. Primary care	167866
	22. Primary-based care	2
	23. Primary healthcare	157684
	24. Community healthcare	120024
	25. 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24	380639
	26. Interventions	529463
	27. Evaluation	1931730
	28. Implementation	280930
	29. Effectiveness	753881
	30. 26 or 27 or 28 or 29	3177830
	31. 7 and 16 and 25 and 30	**560**
CINAHL		**15**
MEDLINE (Ovid)		**153**
PubMed		**196**
PsycINFO (Ovid)		**7**
Scopus		**315**
Web of Science		**474**
Total records		**1,720**

3.8.4 Inclusion and exclusion criteria

Inclusion and exclusion criteria are presented in Table 6. Primary studies of any design that reported on community HIV management described as person-centred delivered or led by HCP were included.

Table 6: Review inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Primary studies of any designs reporting models of person-centred care for PLWHA led by formally trained HCP and delivered in the community • Studies of adults aged 15 years and above [246]. • Studies published from 1980 to date.	• All studies of any design reporting on HIV testing/ counselling/ adherence only would be excluded. • Studies reporting on CBHS for children and adolescents (from age 0-14 years) • Any CBHS neither delivered by nor/ led by professionals will be excluded. • Editorials, opinion pieces, conference abstracts, descriptive studies, case studies and reviews. • Studies presenting adjunct services only, without management of HIV disease.

3.8.5 Data collection and extraction

The first reviewer (MA-O) imported all search results to Endnote version X9, removed all duplicates, then screened titles and abstracts of all identified studies. Studies retained after removing duplicates were screened against the inclusion/ exclusion criteria, any article for which inclusion was unclear were discussed with a second reviewer (KB) and if necessary adjudicated by a third reviewer (RH). Full texts of the articles were obtained if abstracts did not contain sufficient information to determine the relevance of an article. Information of search records including duplicates, exclusions and studies retained were reported using the PRISMA flow diagram. We extracted studies that used the term ‘person-centred’, including alternative spelling or synonyms (see search terms). Studies not meeting the inclusion criteria were excluded. Data on study location, aim design/ sample size, care structure, processes, person-centred and clinical components delivered, outcomes/ measures used, and findings were extracted into a common table. Countries where studies were conducted were classified using the World Bank classification system [247].

3.8.6 Quality appraisal of studies included

MA-O assessed the quality of studies included using the Standard Quality Criteria for Evaluating Primary Research papers [244]. This tool was used to assess the quality of both quantitative and qualitative studies separately. The checklist for assessing the quality of quantitative studies assessed 14 domains of methodological quality of all the quantitative studies included of which points were allocated based on the presence or absence of a domain. The presence of a domain is scored 'YES' (2) and when a domain is partially described it was scored as 'PARTIAL' (1) and the absence of a domain is scored 'NO' (0). The domains assessed have been summarised in Table 7.

The methodological quality for qualitative studies were assessed based on 10 domains (see Table 8 for the domains assessed). After these domains were assessed the total sum scores were then calculated as the final quality score for each study, which ranges from 0 to 1. A total quality score of 0 is the lowest score, and 1 is highest score. Data quality for the included studies were reported in the data extraction table, and studies were not excluded from final analysis based on their quality scores. This quality assessment tool was chosen for its strength in assessing the quality of both quantitative and qualitative studies.

Table 7: Quality domains assessed for quantitative studies, adapted from Kmet et al. [244]

Criteria		**YES (2)**	**PARTIAL (1)**	**NO (0)**	**N/A**
1	Question / objective sufficiently described?				
2	Study design evident and appropriate?				
3	Method of subject/comparison group selection or source of information/input variables described and appropriate?				
4	Subject (and comparison group, if applicable) characteristics sufficiently described?				
5	If interventional and random allocation was possible, was it described?				
6	If interventional and blinding of investigators was possible, was it reported?				
7	If interventional and blinding of subjects was possible, was it reported?				
8	Outcome and (if applicable) exposure measure(s) well defined and robust to measurement / misclassification bias? Means of assessment reported?				
9	Sample size appropriate?				

10	Analytic methods described/justified and appropriate?				
11	Some estimate of variance is reported for the main results?				
12	Controlled for confounding?				
13	Results reported in sufficient detail?				
14	Conclusions supported by the results?				

Table 8: Quality domains assessed for qualitative studies

Criteria		**YES (2)**	**PARTIAL (1)**	**NO (0)**
1	Question / objective sufficiently described?			
2	Study design evident and appropriate?			
3	Context for the study clear?			
4	Connection to a theoretical framework / wider body of knowledge?			
5	Sampling strategy described, relevant and justified?			
6	Data collection methods clearly described and systematic?			
7	Data analysis clearly described and systematic?			
8	Use of verification procedure(s) to establish credibility?			
9	Conclusions supported by the results?			
10	Reflexivity of the account?			

3.8.7 Analysis

Summary of studies identified were reported using the PRISMA flow diagram. Data were extracted and analysed using the Donabedian framework of quality [175]. These variables were considered relevant to answering the review questions and were extracted to a common table, including aims/objectives design and sample size, care structure, processes, person-centred and clinical components delivered, outcomes and measures used, including results and effectiveness. Studies were also mapped based on the components of PCC delivered by each study in a table to identify the domains delivered for each model across studies. Descriptions of PCC models were analysed based on Mezzich's definition of PCC. Both qualitative and quantitative studies were analysed descriptively, and then findings integrated. All studies addressing any component of PCC were retained in the final analysis.

Gaps in the literature with regards to person-centred models of community HIV management were used to inform a qualitative topic guide that was used to explore the views of PLWHA and HCP. The models delivered and their effectiveness in delivering the outcomes that mattered to PLWHA were also considered in addition to the outcome measures used by the identified studies in measuring study outcomes. This review also helped to provide information on the effectiveness of existing person-centred interventions, their variations in terms of context, the outcome measures used, their feasibility and acceptability including mechanisms of action [248], which were adopted to inform the proposed intervention.

3.9 Phase 2: Thesis objective 2

(**MRC Development stage: 'Identifying/ developing appropriate theory'**)

To explore the views of PLWHA and healthcare professionals (HCP) on current HIV/AIDS care, its accessibility, and to determine which person-centred outcomes matter to PLWHA.

Research question associated with thesis objective 2 is:

What are the views of PLWHA and HCP on current HIV care, its accessibility, and what person-centred outcomes matter to PLWHA?

3.9.1 Study design

Findings from the systematic review including gaps in the literature with regards to person-centred models of community HIV management and PCC components delivered were used to inform a qualitative topic guide that was used to explore the views of PLWHA and HCP.

A qualitative study using semi-structured interviews, reported in accordance with the consolidated criteria for reporting qualitative research (COREQ) [249] to enhance trustworthiness and transparency of findings.

3.9.1.1 Inclusion and exclusion criteria

Inclusion for PLWHA

- Adults from aged 20 years and above [250];
- A positive diagnosis of HIV/AIDS, known by the patient for at least 6 months to ensure that PLWHA has the experience of care to reflect on;
- Have cognitive ability to consent to participate in the study as assessed by the treating clinician.
- Well enough to participate

Exclusion for PLWHA

- Living with HIV/AIDS under aged 20 years;
- Diagnosed less than 6 months or less;

- ❖ Do not have cognitive ability to consent;
- ❖ Assessed by the treating clinician to be too ill to participate;
- ❖ Attending the clinic for pre-testing or counselling services only.

Inclusion for HCP

- ❖ HCP including doctors, nurses, pharmacists, counsellors, social workers, care assistants, laboratory technician, and human resource manager);
- ❖ HCP providing care for PLWHA for at least six months.

Exclusion criteria for HCP

- ❖ HCP who have worked with PLWHA for less than six months.

3.9.1.2 Sample size

Purposive sampling focuses on the key characteristics of individuals in order to select participants that will reflect diversity and breadth of the sample population [251, 252]. Qualitative methods enable a depth and breadth of exploration and seek to achieve saturation across the data set to answer the study objectives. It was anticipated that 25 PLWHA and 15 HCP would be adequate to achieve saturation in the present study, although an iterative approach to data collection and analysis was adopted to inform this decision. Saturation occurs when the sample generates enough data to ensure the research questions can be answered [253, 254].

3.9.1.3 Sampling

A purposive sampling frame was employed to select PLWHA and HCP for a semi-structured interview. Purposive sampling, (also known as judgmental, selective, or subjective sampling), is a form of non-probability sampling in which researchers rely on their own judgment to choose members of the population to participate in their study [255]. This sampling method requires researchers to have prior knowledge about the purpose of their studies so that they can properly choose and approach eligible participants. Purposive sampling was chosen because the researcher wanted to ensure the recruitment of a wide range of patients in order

to understand their viewpoints on the topic of person-centred care. The risk of using snowball sampling is that the researcher would keep finding new patients who are similar to the ones already interviewed. Also, using convenience sampling means that the researcher would have no control over which patients are recruited resulting in the risk of recruiting a very homogenous sample. Purposive sampling, however, gave the researcher the flexibility to decide what needs to be investigated and sets out to find potential participants who can and are willing to provide the information by virtue of knowledge or experience. In addition to knowledge and experience, potential participants must also be available, and willing to express their experiences to the interviewer. Unlike random studies, which deliberately include a diverse cross section of ages, backgrounds and cultures, the idea behind purposive sampling is to concentrate on people with particular characteristics who will better be able to contribute to the purpose of the study [207, 251, 256]. The sampling characteristics that informed the purposeful recruitment of PLWHA include gender, sexual orientation, ART status, years of diagnosis, CD4 count, viral load, comorbidities, level of family/friend support, and employment status. These sampling characteristics were chosen because they are considered important characteristics that may affect an individual's ability to access and meaningfully engage with services [256-258]. These characteristics also helped to achieve breadth in the data required to answer the study objectives.

The sampling frame that informed the purposeful recruitment of PLWHA are presented in Table 9, including gender, sexual orientation, ART status, years of diagnosis, CD4 count, viral load, comorbidities, family/friend support, and employment status. This sampling frame is of interest to the researcher to sample from the population of PLWHA and was chosen because they are considered important characteristics that may affect an individual's ability to access and meaningfully engage with services [257-259]. The sampling frame was also used in order to achieve breadth in the data required to answer the study objectives.

Table 9: Sampling framework for recruiting PLWHA

Criteria	**Variable / range**
Gender	Male /female /transgender /other
Sexual orientation	Lesbian /MSM /bisexual /heterosexual
ART status	Active/ defaulter /not yet started
Years of diagnosis	6months or more
CD4 count (cells/mm^3)	<200 cells/mm^3 / >500 cells/mm^3
Viral load (copies/mL)	High or Undetectable
Comorbidities	Hypertension/ cardiovascular/ kidney/diabetes etc.
Living situation	Lives alone/with others
In employment	Yes/No

3.9.1.4 Recruitment and consent

Potential PLWHA participants who met the inclusion criteria were identified daily by the HCPs in both clinics, who then referred these participants to the researcher for further screening. Rapport was built with potential participants as the researcher took part in their daily health screening (weight, height, etc.). Doing this gave the researcher the opportunity to introduce the study to potential participants and invited them to take part in the study. Those who agreed were taken through the study information (APPENDIX G), giving an opportunity for further discussion about the study and answered any question or concerns that potential participants had. Where possible, a quiet environment was sought to do this. However, this was not always possible and at times these conversations were held in a busy clinic waiting room. There did not appear to be any difference in the questions that were asked or refusal to participate when this occurred. Any questions that participants had were answered before obtaining consent. Potential participants were informed that their choice to participate or not to participate in this study would not affect their care and treatment, and that if they decide to participate in the study, they were free to withdraw at any time they wished. Potential participants were given up to 24 hours to decide whether they wanted to participate in the study. Participants who decided to take part in the study were taken through the consent processes by the researcher.

Participants either signed or thumb printed the consent forms (APPENDIX H) to prove their willingness to participate in the study. The sampling frame was monitored closely as recruitment progressed; this was to ensure diversity of the sample according to the purposive sampling criteria.

HCP were identified by the clinical team and the researcher contacted them through e-mail to introduce the study by sending them the information sheet (APPENDIX I). HCP participants were given the opportunity to discuss or seek clarification about the study, were given the required information, and once they were satisfied and willing to participate, they signed the consent form (APPENDIX J). Potential participants were informed that their choice to participate or not to participate in this study was voluntary, and that they were free to withdraw at any time they wished.

3.9.1.5 Interview procedure

The interview process began by assuring participants that all data would be anonymised and kept completely confidential and only accessible to the research team. Participants were made aware that the interview would be audio recorded and that if there were any questions that the participant did not wish to answer, then they could choose to omit or terminate the interview. Also, participants were made aware that if they required a break or wanted to stop the interview at any time, they were free to do so. Digital recording of interviews allowed the researcher to fully pay attention to PLWHA and HCP and their non-verbal cues without the need to take extensive notes during the interview and allows verbatim quotes for accuracy [260].

All participants were interviewed face to face on their own, allowing the researcher to establish rapport with participants, using the researchers' interpersonal skills in obtaining personal information and promote participants' privacy and confidentiality [261]. The researcher considered the type of questions asked and thoroughly discussed issues with confidentiality in order to maintain trust and respect for participants through professionalism [262]. Interviews were conducted in participants' respective clinics.

3.9.1.6 Interview topic guide

An interview topic guide was developed based on literature, theories, study objectives [263, 264], and discussion with supervisors (RH and KB) who have experience of developing interview topic guides for PLWHA and in qualitative interviewing. Constructs from the theory of person-centred care and literatures on HIV care, were included in the wording of questions in the interview topic guide [265]. The topic guide was divided into three sections: section A – introduction about the interview and what the participant should expect; section B – focussed on participants demographics and areas of interest including age, gender, relationship status, religion, ethnicity, occupation, level of education, years of diagnosis, ART status, viral loads, CD4 counts and the presence of comorbidities; and section C – was organised based on four areas of interest being explored namely 'place where you receive standard HIV/AIDS care', **'**HIV/AIDS care interaction with healthcare professionals', 'HIV/AIDS symptoms and concerns (Physical, Psychological, Social and Spiritual wellbeing)' and 'person-centred care/ involvement in care'. There were two separate topic guides: one for PLWHA (APPENDIX K) and the other for HCP (APPENDIX L). These guides were tested out with another researcher and modified based on feedback received. They were then piloted for flow and comprehensiveness with two participants prior to data collection. The interviews were semi-structured so although the topic guide provided direction and highlighted areas that needed to be addressed, it also allowed the participant the freedom to expand on priority areas for them.

The topic guide began with a general exploration of participants' place of standard HIV care (SHC) including challenges of accessing care and interaction with HCPs. Probing and questions about living with HIV/AIDS and symptom burden (physical, psychological, social and spiritual wellbeing); and person-centeredness in HIV/AIDS care were left till the middle of the interview. This was to allow participants to relax and become accustomed to the interview surroundings and the interviewer. All issues were explored paying careful attention to verbal and non-verbal cues and pauses. Participants were warned that the interview was coming to an end to allow them to discuss any issues not covered by the interview but that they felt were important. Interviews were concluded with questions about what matters to participants when considering a new approach to HIV/AIDS care in the community. At the end of the interview,

the researcher summarised the interview to ensure that participants agreed with what has been discussed and offering an opportunity to clarify any information that was not clear, and further assured participants of confidentiality. Refinement of the interview process continued as each subsequent interview was completed through listening back and reading transcripts throughout recruitment.

The researcher had not previously conducted qualitative interviews. Therefore, in preparation, the researcher did extensive reading and practice interviews with peers (JB and SP) who provided constructive feedback. The researcher also attended a qualitative interview skills workshop where lessons were learnt on picking up verbal and non-verbal cues and following them up appropriately with the use of silences and gentle probing. The researcher practiced, discussed and made plans of how to handle distressed participants with supervisors KB and RH. This enabled the researcher to gain confidence and skills in this new area of expertise. Initial interviews conducted by the researcher were transcribed and reviewed by supervisors KB and RH, who provided feedback on transcribing technique, interview skills and content.

In conducting the interviews, it was necessary for the researcher to build rapport with participants, particularly PLWHA whom the researcher hoped to elicit sensitive information from. This involved the researcher gaining their trust and confidence which necessitated some emotional input from the researcher in the relationships [266] and the researcher's awareness of the emotional, practical and physical needs of PLWHA. However, the researcher also recognised the impact of feelings and responses reflected back to the interviewee [266]. There was the need to strike the right balance between empathy and minimizing influence or bias. To facilitate this, the researcher conducted the interviews away from the clinic reception and ensured that participants were comfortable throughout the interview process, including dressing appropriately to reflect respect for the interviewees and at the same time not to look imposing or unapproachable.

3.9.2 Data analysis

A qualitative approach of thematic analysis was chosen for the analysis of this dataset due to its ability to address variety of research questions and topics [267, 268]. NVivo version 11 was also used, which helped to manage and index data according to the coding frames. The

researcher attended an NVivo version 11 course at King's College London which helped to further refine skills in using this qualitative data management package.

Braun and Clarke describe thematic analysis as a method used for 'identifying, analysing and reporting patterns (themes) within the data' [269]. Thematic analysis is a method rather than a methodology because it is not restricted to a particular epistemological or theoretical perspective [267, 269]. Using thematic analysis for this study provided rich and detailed accounts of the interview data, and its flexibility meant that modifications could be made to fit the objective of the study [269, 270]. Thematic analysis is useful for the examination of the perspectives of different research participants, which highlights similarities and differences in generating an insightful understanding of the data [269]. This approach of analysis also helps in summarising key characteristics of large data sets thereby compelling the researcher to adopt a well-structured approach to handling data in order to produce a clear and organised report [270].

This analysis used the six phases of thematic analysis recommended by Braun and Clarke [269]. These include: familiarisation with the data, generation of initial codes, searching for themes, reviewing themes, defining and naming themes and to producing a report [269, 271].

i. ***Familiarisation with data***: The process of familiarisation with data is the initial phase of thematic analysis. This phase is aimed at becoming intimately familiar with the content of the data set and to begin to notice patterns that could be relevant to the research question. This took several weeks of transcribing the interview data verbatim, reading and re-reading transcripts, in addition to making reflective comments on the content and nature of the interviews. The process of transcription was time consuming however it helped the researcher to be well familiarised with the data [272] and participants' experience of care as PLWHA. This process has been described as 'a key phase of data analysis in interpretative qualitative methodology' [273]. Although the researcher conducted these interviews and had gained an overall impression of the data collected, the researcher felt it was important to set ideas into context and to ensure that recollections were impartial. As the researcher became familiar with the data, notes were made as memory aids and triggered for coding and

analysis and line by line coding was started manually to mark the beginning of the coding process [268].

ii. ***Generating initial codes***: The next step of the analysis was the generation of initial codes from the data set. The codes are a label of an important feature of the data which is of potential relevant to the research question, it is both a data reduction method and an analytic process [274]. These codes were referred to as 'potential' because this was the early stages of data analysis, and it was not known what might be relevant. Consequently, the researcher was as inclusive as possible in coding every interview, as it is easier to reduce the coding frame at a later date if required, rather than having to recode the data. The components of the theory of person-centred care which is, care that promotes health as a state of physical, psychological, social and spiritual wellbeing [216]; and the WHO's five strategic goals for integrated people-centred health services [26] were the constructs used to identify deductive codes. The initial coding frames generated were appraised by two independent researches (LC & SE) who coded the same transcript. The codes generated by LC and SE were the same as the initial coding frame though they differed in the way codes were named. The three researchers reviewed the proposed coding frame for internal consistency of each proposed code, which involved merging and splitting of codes and ensuring that each code is substantive and represented a discrete data theme [263, 269]. The researchers then reached agreement through discussion [271]. Every data item was coded, and all codes and relevant data extracts were collated using NVivo version 11.

iii. ***Searching for themes***: Data analysis began to take shape as the researcher moved from codes to themes. Themes are coherent and meaningful phrases or sentences that demonstrates the meaning of the data and its relevance to the research objective [269]. Searching for themes involved analysing codes to identify similarities and how different codes could combine to form an overarching theme; this was an active process where the researcher constructed themes and collated all the coded data

relevant to each theme [269, 274]. The researcher then considered how relationships were formed between codes and themes and between different levels of existing themes. Visual models of this process helped to sort out different codes into themes [269]. Some of the initial codes went on to form main themes, sub themes or were discarded. This stage of analysis was completed with the grouping of main themes, sub-themes and other miscellaneous themes that did not fit into the main themes.

iv. ***Reviewing themes****:* This involved checking that themes function in relation to the coded extracts and the full data set [269]. The researcher then reflected on whether the themes told a compelling and a convincing story about the data and began to describe the nature of each theme and the relationship between themes. Connections between overlapping themes served as significant sources of information and alerted the researcher to the possibility of new patterns and issues in the data. Where necessary themes were split into two or more themes, collapsed two themes together or discard the main theme entirely and started the process of theme development again.

v. ***Defining and naming themes***: This phase represented the deep analytic work undertaken in thematic analysis, and it was key to the shaping and refining of the analysis. This involved selecting extracts to present and analyse and then setting out the story of each theme with or around these extracts. Here the researcher identified the 'essence' of what each theme meant [269], particularly how the sub-themes interact and relate to the main theme. A comprehensive analysis of each theme was undertaken by asking the question 'what story does this theme tell?'; and the importance of each theme were identified by constructing a succinct name and summary for each theme [274].

vi. ***Writing up/ producing a report***: Even though the final phase of this analysis was to produce a report in the form of a journal article or thesis, it was not a phase that only commenced at the end of the analysis. Unlike in quantitative studies, writing and analysing data are systematically interlaced in qualitative studies, which begins with

informal notes and memos to a more formal process of analysing and writing a report. This report is expected to tell a compelling story that is grounded in the data and based on the analysis, with themes connecting logically and meaningfully and building on earlier themes in telling a coherent story about the data. Additionally, this report should meaningfully contribute to answering the research question.

3.9.3 Presenting the results

The same coding frame was applied to HCP and PLWHA datasets, to enable the exploration of themes across participant groups. Quotes from the transcripts were used to demonstrate data interpretation. This also helped to increase transparency of the analysis process and prevented unsupported claims, and to ensure the themes are represented across the dataset and participants [269, 275]. Data extracts were selected carefully to elaborate aspects of the findings and to deepen understanding to enhance readability [275]. Extracts were chosen from both PLWHA and HCP interviews to ensure that everyone's view was represented. Each extract was reported with the corresponding participants' gender, age and group (PLWHA or HCP). Participants quotes were selected across the sample and ID codes were used to illustrate themes as well as demonstrate that these quotes did not come from just one or few participants.

3.9.4 Trustworthiness in qualitative research

The usefulness and integrity of the findings of a qualitative research is dependent on the transparency of its conduct and trustworthiness or truth value of the study [276]

The degree of confidence in data, its interpretation, and the methods used to ensure the quality of a study is termed trustworthiness [277]. Therefore, it has been argued that for studies to be considered worthy by readers it is crucial for researchers to establish the protocols and procedures required in conducting them [278]. However, there are debates about what constitutes trustworthiness [279]. Therefore, Lincoln and Guba outlined some criteria such as credibility, dependability, confirmability, and transferability [280, 281] for qualitative researchers in pursuit of trustworthiness. The rationale for choosing to address Guba's criteria for this study is because it is consistent with the criteria used by the quantitative researchers:

- credibility (relates to internal validity);
- dependability (relates to reliability);
- confirmability (relates to objectivity).
- transferability (relates to external validity/generalisability [281]) .

Although Lincoln argued that the area of qualitative research was “still emerging and being defined” [282], many qualitative researchers have accepted Guba’s criteria. These criteria as applied to this thesis has been discussed in turn.

3.9.4.1 Credibility

The confidence that can be placed in the truth of the research findings is termed credibility [283, 284]. Credibility is established when research findings are considered believable as drawn from participants’ original data and represents participants’ original views [280, 285]. Strategies to ensure credibility as described by Lincoln and Guba may include: prolonged engagement in the field, persistent observation, triangulation, peer debriefing, referential adequacy and negative or deviant case analysis [280]. For this thesis prolonged engagement in the research site and peer debriefing were used to enhance credibility.

Prolonged Engagement in Research Site: The researcher engaged with PLWHA and HCP for 3 months whiles collecting data which allowed for some form of immersion in the environment of PLWHA and HCP working in HIV service [286]. This helped the researcher to understand the study context and minimised the risk of misrepresentations. The extended time spent by the researcher with study participants in the research site resulted in trusting relationships with participants and provided greater understanding of participants’ culture, preferences and context [287]. The prolonged time spent with the participants was very beneficial in the sense that as relationship and trust increased, participants felt comfortable to share sensitive information than they did at the start of the study [287]. Thus, this prolonged engagement with participants helped the researcher to understand the fundamental issues that could affect the quality of the data and to develop trust with study participants.

Peer debriefing: The researcher continuously availed herself for the thesis progression committee to be questioned about judgements made about study data including being exposed to probing questions from other PhD colleagues who have listened to the researcher

present study data, analysis and results [280]. The researcher also sought support from colleagues and members of the academic staff, who were impartial to the study to help with coding some interview transcripts during data analysis for consistency and to enhance credibility of the process. My supervisors constantly provided scholarly guidance in addition to other members of staff during researchers exchange at the department. Feedbacks received from peers and other members of staff helped to improve the quality of study findings. Consequently when the final report of the study was drafted in the form of a manuscript, perception of peers and co-authors were sought, particularly on the study background, data collection process and methods, data management, transcripts, data analysis procedure and study findings [280, 288].

3.9.4.2 Dependability

Dependability is how study findings can be trusted over time [289], and it involves the evaluation of study findings, its interpretation and recommendations made to ensure that they are supported by participants' view expressed in the data [290]. Criteria for establishing dependability include audit trail, a code-recode strategy, stepwise replication, triangulation, and peer examination or iterator comparisons [291-293]. In this study an audit trail strategy was used to enhance dependability.

An Audit Trail: Audit trails involve a transparent description of how data was collected and analysed [294, 295]. For this thesis, the study protocol, including the various methodological decisions taken in conducting the study, models developed, and conclusions drawn based on data serve as an audit trail in the project journal [280, 296-298]. This audit trail demonstrates how the systematic review conducted to identify the evidence base informed the qualitative interview topic guide that was used to conduct the qualitative interviews. The audit trail also shows how the interview data was used to develop a conceptual model of person-centred care from the perspectives of PLWHA and HCP which increases transparency, allowing an auditor to trace the process of decision making and determine whether the decisions were reasonable and consistent and therefore the findings trustworthy [299, 300]. Confirmability is indicated when the decisions taken in relation to the evidence presented is coherent. Having two independent researchers code some of the interview transcripts concurrently, and checking

inter-rater reliability, increased the dependability of findings. This clarified any confusion or misunderstanding, which is an added value to the study as each coder brought their own interpretive framework [299-301]. This also meant that interpretation was determined by the coders experience, theoretical background and discipline among other factors, which highlighted the subjectivity acknowledged to be an integral part of qualitative research [299, 300].

For this study, the raw data, interview transcripts, observation notes and records collected during the conduct of this study collectively serve as an audit trail for crosschecking the inquiry process [302]; which also establishes confirmability of the study [302, 303].

Peer Examination: The researcher discussed the study process, methods and findings with PhD colleagues at PhD support group meetings of whom some have also conducted qualitative studies or have experience in qualitative studies. During the peer examination the researcher was honest about the conduct of the study and peers contribution led to a deeper reflexive analysis by the researcher [304, 305].

3.9.4.3 Confirmability

The degree to which the findings of this study could be confirmed by other researchers is termed confirmability [306]. Confirmability is to be able to prove that study data and interpretation of the findings reflect participants' view as expressed in the data and not fabricated by the researcher [303]. Confirmability of qualitative studies can be established using an audit trial, reflexive journal and triangulation [280, 294, 307]. The researcher used audit trail and reflexive journal to enhance the confirmability of study findings.

The audit trail described under 'dependability' is a visible evidence from the methods used to conduct the study to the findings, that the researcher had gone through due process to achieve the results of the study [294].

Reflexive Journal: The researcher kept a reflexive journal during data collection and analysis process. Among the entries recorded in this journal include the researchers' perception of the participants and how participants behaved during the interviews in addition to how they spoke. These records helped the researcher to recall the meanings of what participants said at the interviews during the data analysis process and identified any distractions or comments the

researcher felt were important to the findings. The reflexive journal is subjective data source where the researcher recorded all personal impressions that could possibly impact on the analysis procedures. By recording this subjective information, it was possible for the researcher to take note of what should be guarded against regarding subjectivity during data analysis. For instance, there was the possibility that the researcher had negative subjective responses to participants who expressed that person-centred care or involving PLWHA in their care decisions was not important because HCP will make the decision for them. Records made about these negative responses in the reflexive journal provided a "place" in the study for the researcher's perceptions.

3.9.4.4 Transferability

Transferability refers to the extent to which the study findings are applicable to other contexts, settings or population [303, 305]. Transferability of this study was enhanced through some level of transparency demonstrated by 'thick description' and 'purposeful sampling' [280, 305]. In this thesis a detailed descriptive account of the study and the purposeful selection of participants was used to enhance transferability.

Thick description: A detailed description of study processes, context, methodology through to the writing of final study report determines judgments about how well the research context fits other contexts [295]; including the use of longer quotes that provide the context for the quote. This descriptive account for this study can be found in section **3.9.1** within this section of methods and section **5.2.4** in the results section. This thick description could help other researchers to be able to replicate this study with similar conditions in other contexts, as it has been argued that without this thick description it will be difficult to accept the truth value of the final report [308].

Purposive Sampling: Purposive sampling was used to identify and select participants who have the information to contribute the specific purposes of the research [309]. This helped the researcher to focus on group of participants, who were particularly knowledgeable of the phenomenon under investigation [310], because purposive sampling allows decisions to be made about the selection of participants [292, 311]. Purposive sampling allowed the

researcher to decide the a reason to use a specific category of PLWHA in the study [311], and it provided greater in-depth findings than other probability sampling methods [312].

3.10 Phase 2: Thesis objective 3

To map the qualitative data from objective 2 onto the components of person-centred care theory to determine which components map and what extra components are required.

The research question associated with thesis objective 3 is:

What are the components of person-centred care as applied to PLWHA in Ghana and how do these components align with the theory of person-centred care?

3.10.1 Adaptation of Person-centred theory

The person-centred care theory was adapted alongside the identification of the evidence base in Phase 1 of this PhD. The MRC guidance emphasise the need to systematically develop interventions 'using the best available evidence and appropriate theory' [178, 313]. Evidence suggests that interventions that use theory are more likely to be effective [314]. Therefore, the theory of person-centred care (PCC) was identified and chosen to underpin this PhD. Since PCC is context specific and has been defined differently in different settings, the definition of PCC chosen for this PhD is one that is 'dedicated to the promotion of health as a state of physical, mental, sociocultural, and spiritual well-being, as well as to the reduction of disease, and founded on mutual respect for the dignity and responsibility of each individual person' [146]. This definition of PCC was chosen to reflect the domains of need experienced by PLWHA and the focus on holistic care delivery. PLWHA frequently experience highly distressing physical, psychological, social and spiritual symptoms and concerns [5, 102-104], which negatively impact on their quality of life [105]. Greater attention has been paid to viral suppression at the expense of broader psychological, social and spiritual concerns that persist despite treatment advances [5, 106]. To address these issues, holistic assessment and PCC is required. The holistic and PCC approach to care delivery addresses physical, psychological, social and spiritual symptoms and concerns thereby restoring balance and enabling patients to cope with their conditions and subsequently improve their lives [315]. Figure 10 is a depiction of the components of person-centred care theory chosen to underpin this study.

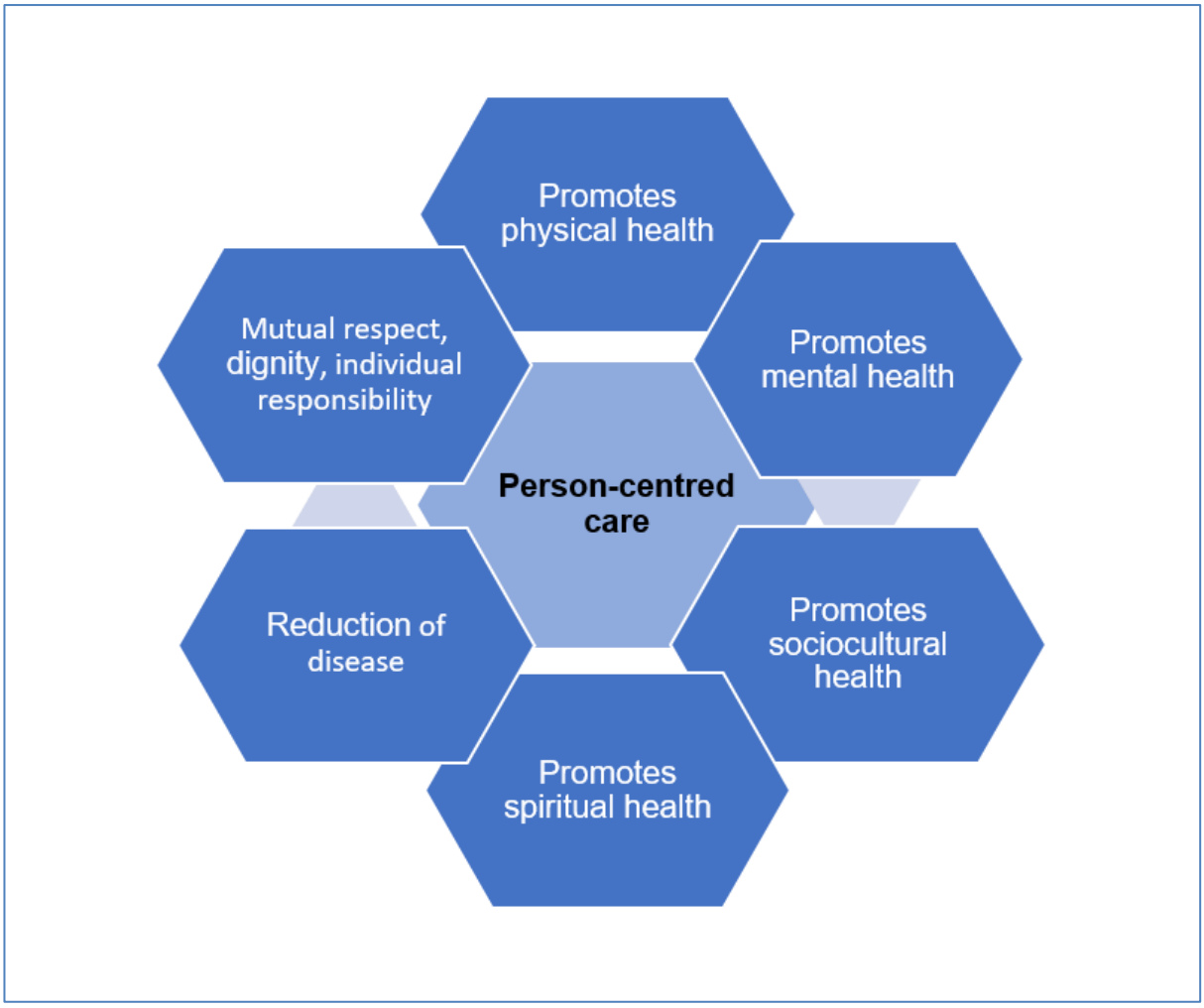


Figure 10: The components of person-centred theory as defined by Mezzich [146]

3.10.2 Mapping person-centred care components onto person-centred theory

The qualitative interviews conducted with PLWHA and HCP in thesis objective 2, identified person-centred care (PCC) components/ needs as applied to PLWHA in Ghana. These needs were mapped onto the components of the PCC theory (in an expert intervention development workshop discussed in section **3.11.1**), to determine which components mapped onto the theory with the flexibility of adding additional components if required. Mapping the theory onto the components/ needs as applied to PLWHA was crucial as the outcome of the mapping helped to identify what was important, applicable and feasible in informing the intended objectives, content and delivery of the intervention [316]. The theory selected provides explanation for how a range of modifiable factors can be targeted by a person-centred intervention component to achieve outcomes that are meaningful to PLWHA. These factors

are influenced by each participants' unique context: their sociocultural beliefs around HIV/AIDS, physical, psychological and spiritual symptoms and concerns, the presence of comorbidities, stigma and discrimination as discussed during the intervention development process in section **3.11.1**.

3.10.3 Integration of data from thesis objectives 1-3

Data from the findings of thesis objectives 1, 2 and 3 were integrated including PCC models delivered in community settings for PLWHA alongside the identification of the theory of PCC, and qualitative interview study of HCP and PLWHA in Ghana. Several important considerations for intervention development emerged from both the systematic review and the qualitative data. The experiences of PLWHA and HCP shared in the qualitative data provided important understanding of the context where care delivery for PLWHA occurred, which was used to tailor a PCC intervention. For instance, issues around the care structure, processes of care delivery and expected outcomes, which were consistent with the findings from the systematic review. Outcome measures used in some of the identified studies in the systematic review were also considered in terms of their appropriateness in measuring person-centred outcomes for PLWHA when considering the development of a person-centred intervention for PLWHA. Components of the intervention were also considered in the light of the systematic review, the PCC theory and the qualitative data. These data sources were integrated to form the intervention components, which reflected the outcomes that mattered to PLWHA and the process and outcome measures used in measuring the intended outcomes of the proposed intervention developed in thesis objective 4.

3.11 Phase 2: Thesis Objective 4

"Modelling process and outcomes"

To integrate findings from objectives 1-3, modelling the potential processes and outcomes, and the potential mechanism of action of the intervention.

The research question linked to thesis objective 4 is:

How does the integration of findings from objectives 1 to 3 inform the intervention development, its potential modelling processes and outcomes, and the potential mechanism of action of the intervention?

3.11.1 Intervention development process

This section details the steps taken to integrate findings from thesis objectives 1 to 3 with intervention development experts at a workshop in order to develop the enhanced care intervention. This also included modelling the potential processes and outcomes (including selection of outcome measures) and the potential mechanism of action of the intervention to improve person-centred outcomes for PLWHA. It has been argued that the best way to develop interventions is through partnerships with researchers, the affected population, policymakers and interdisciplinary teams of practitioners [317]. Therefore, the researcher made use of research evidence, an expert intervention development panel (including researchers, epidemiologist and educationalist) and the person-centred needs of PLWHA and HCP as identified in a qualitative interview study to develop this intervention. This is because the ability of the intervention to address the perceived needs of PLWHA leading to its acceptability; practicality; evaluability, including the theorising of causal pathways; and uptake by practitioners and the possibility of intervention effectiveness is dependent on such coproduction.

Wright et al.'s [317] six steps in quality intervention development was used to guide the development of this intervention. These six steps include: (i) defining and understanding the problem and the cause, (ii) clarifying which contextual factors are pliable and have the greatest scope for change, (iii) Identification of how to bring about change (the change mechanism),

(iv) identifying how to deliver the change mechanisms (v) Testing and refining on a small scale, and (vi) collecting sufficient evidence to justify rigorous evaluation/implementation. This section (thesis objective 4) described the first four steps and the last two steps are described in the next section (thesis objective 5).

Step (i): Defining and understanding the problem and the cause - The first step in intervention development is to clarify the problem using existing evidence [317, 318]. This also involves collating research evidence from stakeholders on a specific health problem in a specific context to understand the cause of the problem that needs to be addressed. The aim of understanding the contextual health problem is to develop an intervention that helps to reduce the impact of the problem [319]. Thesis objectives 1, 2 and 3 all explored PCC models delivered in community settings for PLWHA, and particularly in the context of Ghana. During this stage of defining and understanding the health problem and the cause, the intervention development experts, were not involved. In Phase 1, the researcher conducted a systematic review to identify domains of PCC delivered in community settings for PLWHA, the care structure, processes of care delivery and outcomes achieved. This review also helped to provide information on the effectiveness of existing interventions, their variations in terms of context, outcome measures used, their feasibility and acceptability including mechanisms of action [248], which could be adopted to inform this intervention. Few published studies were identified delivering PCC models in community settings for PLWHA, which addressed the domains of physical, psychological, social and spiritual wellbeing [320, 321]. Evidence suggest that PLWHA perceive that their care does not often address broader psychological, social and spiritual concerns, which persists despite treatment advances [5, 106]. Consequently, the researcher identified a PCC theory that focused on the domains of PCC described in the literature and adopted this theory for the intervention development.

The researcher identified the existing research evidence and adopted a person-centred theory which underpinned the intended intervention [322] as described in the thesis background. The definition of PCC theory chosen for this PhD focus on holistic care that promotes physical, psychological, social and spiritual wellbeing alongside reduction of disease, as experienced by PLWHA. Selman et al. noted the importance of holistic assessment to achieve PCC for

PLWHA, noting that spiritual wellbeing receives less attention [155]. This theory is expected to translate to practical application, for instance the components of the person-centred theory should translate into practical intervention elements that fits the context and the target population (PLWHA) attributes [319]. This theory helped to clarify PCC models in order to understand the problem with the care delivered to PLWHA.

The researcher also understood these problems from the perspectives of PLWHA and HCPs in the context of Ghana in order that this intervention could address the specific contextual problems faced by PLWHA. This was done through qualitative exploration of the views of PLWHA and HCP on standard HIV care delivery and what person-centred outcomes matter to PLWHA [323, 324], using interview topic guides informed by the systematic review in Phase 2, thesis objective 2. Themes emerged describing the problems with the current approach to HIV care delivery, what constituted PCC from the perspectives of PLWHA and HCP; the way PLWHA expected their care to be delivered; what mattered to them most about PCC care delivery; challenges faced by HCP during care delivery; and what HCPs needed in order to deliver PCC for PLWHA. These themes aligned with the PCC models (physical, psychological, social and spiritual wellbeing) described in the PCC theory and as identified in the systematic review in thesis objective 1.

Following the studies identified in the systematic review that delivered the PCC models, they reported improving physical, psychological, social and spiritual wellbeing outcomes for PLWHA [39, 164] although, only one of these studies used validated outcome measures to assess study outcomes [320]. This review also revealed a lack of existing interventions in low or middle-income settings that used models of PCC as an intervention delivery mechanism for PLWHA. PCC models are particularly poorly described in African context [39, 164]. Therefore, merging the systematic reviews with the views expressed by PLWHA and HCP, there was a need to develop a context specific PCC intervention, which could add to the few existing studies currently delivering the models of PCC for PLWHA. This intervention could address the HCP challenges which could improve their approach to care delivery and thereby improving outcomes for PLWHA. Therefore, in the next step in this intervention development, the researcher together with the expert intervention development panel decided to focus the

content of the intervention on the physical, psychological, social and spiritual wellbeing of PLWHA.

Step (ii): Clarifying contextual factors and the scope for change - An expert panel was involved from this stage of the intervention development consisting of researchers, epidemiologist and educationalist with a range of experiences. Panel members expertise included outcome measurement and tool validation, HIV/AIDS care in sub-Saharan Africa and intervention development and testing (RH); educationalist with a PhD that evaluated palliative care training in rural Uganda (JD); priority outcomes for people with HIV/AIDS and communication between health professionals and patients in clinical encounters, and how that interaction shapes the experience for patients and their families (KB); pain and symptom self-management among HIV/AIDS, designing, testing and evaluating nursing interventions (KN); and use of patient reported outcomes measures in clinical settings, knowledge translation, information use and policy development (EN). These experts were assembled based on their wealth of experience in working with PLWHA and developing interventions in this population across Africa. The expert panel met face to face (with EN joining via skype) in a half-day workshop to discuss the evidence identified from the systematic review in thesis objective 1, the qualitative data obtained from the views expressed by PLWHA and HCP, the components of the PCC theory adopted to underpin the intervention development. The agenda for this workshop was for the researcher to present the evidence identified (both from systematic review and qualitative interview study) to determine the need for the intervention, examine current practice and to develop the intervention to address specific contextual needs.

Expert panel discussion during the intervention development workshop

a. *Determination of needs for the intervention* - The researcher presented on the evidence identified from the systematic review with the PCC theory components and qualitative data from stakeholders (PLWHA and HCP). The panel thoroughly discussed the evidence laid before them in order to understand the needs of PLWHA, their preferences, perspectives on PCC and the capabilities of both PLWHA and HCP, which was fundamental for the intervention development. As the goal for the workshop was to

develop an intervention that had the ability to address the problems identified from stakeholders' perspective, and that was feasible to deliver, cost-effective, and replicable. Therefore, the panel examined the studies that delivered PCC models identified in the systematic review including the care structure, processes and the outcomes derived from delivering the PCC models. The panel then discussed and used the qualitative data (which included stakeholder perspectives, preferences and needs for PCC) and mapped it onto the components of the PCC theory. This mapping was done to determine how much of the qualitative data mapped on the theory and if there was a need to add any additional component. The outcome of the mapping provided information on the potential components of the intervention at this stage.

b. *Examining current practice* – In order to optimise the successful delivery of the proposed intervention within the context of Ghana, the panel also discussed current practice as observed by the researcher and as reported by stakeholders during the qualitative data collection. This was aimed at thoroughly exploring the context where the intervention was meant to be delivered in an attempt to identify facilitators and barriers concerning the intervention among PLWHA and HCP so as to augment the practicability of the intervention to closely fit the current practice [199]. Having considered all the evidence (systematic review findings, PCC theory and qualitative data) and the discussions that ensued among panel members, the panel fully named the components of the proposed intervention with only one potential overlap in terms of current practice. The qualitative interviews data helped to maximise the cultural and local suitability of the intervention as recommended by the MRC guidance [176].

Step (iii): Identification of how to bring about change (the change mechanism) - HCP interviews were important in understanding their views on challenges and training needs required to implement the intervention in preparation towards testing and refining the intervention on a small scale. The panel discussion continued on the qualitative data regarding the prerequisite skills required by HCP and how they needed to be trained to deliver the intervention [325]. Based on the qualitative data from HCP and outcomes that matter to

PLWHA, the panel agreed that the content of HCP training is focused on the intervention components and to reflect the domains of need described by PLWHA. Taking into consideration the current context and practice, a schedule and duration for HCP training was discussed and agreed and potential outcome measures to measure the domains of PCC identified, among others. During the intervention development, the researcher and the expert panel gained insight into how the intervention was operational in practice in addition to understanding the dynamics of the implementation context [326]. The panel also discussed the need to draw on existing manuals, documents and procedures that could be adopted in order to develop a comprehensive but simple PCC training manual for HCPs. The panel agreed that palliative care skills might be appropriate to draw on for the training manual development. Palliative care is known to deliver holistic and person-centred care for people facing serious illness like HIV/AIDS, with the goal of improving their quality of life through early identification, assessment and treatment of physical, psychosocial, emotional, and spiritual concerns [43]. The WHO state that 'palliative care is an essential component of a comprehensive package of care for people living with HIV/AIDS because of the variety of symptoms they can experience' [170]. It has also been argued that the effectiveness of palliative care is limited when it failed to provide holistic care contributing to physical, social, spiritual, and emotional suffering [171]. Therefore, it made sense to adopt palliative care skills in the development of the intervention training content.

The expert panel went on to discuss measurable outcomes for the intervention, which at this stage of the intervention development became very clear to the panel members that outcomes was based on the domain of needs described by PLWHA in the qualitative data, which informed appropriate process and outcome measures for evaluating the intervention. An agreement was reached regarding the outcomes and the corresponding measures to be used. Potential process and outcome measures were suggested for which the researcher selected two process and three outcome measures based on their psychometric properties, suitability for use in HIV population and their ability to measure intended outcomes [178]. The expert panel was dissolved at the end of this stage of the workshop; however, it was agreed that the panel was still accessible via e-mail to provide feedback on the logic model and the content of the intervention training until the intervention was manualised for feasibility testing.

Step (iv): Identifying how to deliver the change mechanism - The researcher modelled the components of the intervention and how the care process could deliver these components in order to achieve desired outcomes for PLWHA. A logic model was developed, which demonstrated the casual modelling of the intervention with all its components and linking it with the ToC (person-centred care), the local context, the proposed mechanism of action and with the selected outcome measures measuring the domains of physical, psychological, social and spiritual wellbeing. The set of PCC needs identified from the qualitative data and the mechanism to achieve these outcomes for PLWHA were mapped onto the process and outcome measures selected. Modelling provided a guide to link the process and outcome measures selected to the intervention components for testing [186]. The logic model which is underpinned by the ToC was used to integrate and illustrate the intricate paths within the intervention [327], which helped to clarify the causal assumptions. The approach used in developing the logic model involved identification of a logical flow starting from planned input activities and ended with specific outcomes [327]. The specific logic model was tailored to the characteristics of PLWHA population, their social context, wellbeing and disease outcomes. The ToC, evidence obtained from literature and qualitative data from stakeholders were used to guide the selection of intervention components, training needs of HCP, their expected approach to care delivery and what outcomes to measure [186]. This theoretical modelling helped to understand and simulated the intervention [328] by describing: the active ingredients and how these ingredients worked to effect change; the outcome measures used to assess the effect of the intervention; how the active ingredients related to each other; every key mediators and moderators, and the PCC theory (ToC) which underpinned the effects and related to the intervention implementation [328].

Process and outcome measures selected for the intervention

a. **APCA Palliative Outcome Scale (APCA POS)**: APCA POS is a multidimensional person-centred assessment tool, which was adapted from earlier versions of the Palliative Care Outcomes Scale (POS), validated for use in Africa [329-332] and has been used in HIV population. It is a seven-item (patient only) measure covering physical, psychological, social and spiritual dimensions of care. APCA POS also has three items which focus on

the carer of the patient however, this study was not designed to include carers therefore the carer items were not assessed. Participants could respond verbally, or by use of their hand to indicate the severity of each symptom and concern, with each finger counting as a point on the Likert scale, and a closed fist as 0. Scoring is on a Likert scale of 0-5, from no symptom or concern to overwhelming symptom or concern for each item. Four items on the APCA POS use 0 to indicate the worst symptom or concern, where there are symptom or concern; and three items are also scored in the reverse, where 0 represents best state of health or no symptom or concern. This is to ensure that participants paid attention to all items or questions. The validation involved 682 patients and 437 family carers, interviewed in 8 different languages. Phase 1 - Qualitative interviews (n=90 patients; n=38 carers) showed POS items mapped well onto identified needs; cognitive interviews (n=73 patients; n=29 carers) demonstrated good interpretation; Phase 2 – POS-Missoula-VITAS Quality of Life Index (MVQoLI) Spearman's rank correlations were low-moderate as expected (n=285); Phase 3 - (n=307, 2nd assessment mean 21.2 hours after first, SD 7.2) Cronbach's Alpha was 0.6 on both datasets, indicating expected moderate internal consistency; test-retest found high intra-class correlation coefficients for all items (0.78-0.89); median time to complete 7 minutes, reducing to 5 minutes at second visit [330]. The las four items on this measure was recoded to align with the remaining items so that they score in the same direction.

b. **Medical Outcomes Study – HIV (MOS-HIV)**: Initially developed from Medical Outcomes Survey (MOS) in 1997 [333], the MOS-HIV has been adapted from the MOS as a quality of life measure specific for HIV positive populations [334]. It is a 35-item self-report quality of life measure, which assesses participants' reported function and well-being in eleven subscales (general health perception, pain, physical functioning, role function, social functioning, energy/fatigue, mental health, health distress, cognitive functioning, quality of life and health transition). It has been validated in the United States [335, 336], several European countries [337], Zimbabwe [338], Uganda [339] and Rwanda [340]. A total of 532 PLWHA (305 PLWHA and 227 with HIV+ liver disease (LD)) were included in the validation study. Although both groups had relatively poor self-reported MOS-HIV physical function, the HIV+LD group had significantly lower scores (p=.018) (M=60.6, SD±31.4) than those

with HIV only (*M*=68.1, SD±29.1). Additionally, persons with HIV+LD had significantly lower self-reported quality of life (*p*=.009), as measured by the MOS-HIV quality of life subscale score (*M*=58.6, SD±24.4) compared to the HIV group (M=62.9, SD±24.0). Spearman's rho correlations demonstrated a moderate correlation between income and all MOS-HIV subscale scores for both groups (r=.300). The Cronbach's alpha as a measure of internal consistency for the MOS-HIV was α=.970 for the HIV group and α=.965 in the HIV+LD group. A multi-group confirmatory factor analysis was performed on the 10 items of MOS-HIV using maximum likelihood estimation with robust adjustments to test for factor invariance between HIV+LD and HIV groups. The combined model showed a good fit [341]. The raw scores for each sub-scale are linearly transformed to a scale of 0-100 according to the guidance from MOS-HIV developers [333]. This measure was mainly chosen because it is disease specific and validated in populations from countries in sub-Saharan Africa. Eleven items on this measure were recoded to align with the rest of the items on the scale.

c. **Picker Patient Experience Questionnaire (PPE-15)**: The PPE-15 [342] is a 15-item self-reported measure which measures patient experience along the domains of communication; emotions; short-term outcomes; barriers; and relations with staff. The PPE-15 can be used to gain feedback on the practitioner-patient relationship across these domains. The PPE-15 is a brief instrument which can be used to examine specific aspects of patient experience. To validate PPE-15, a total of 62,925 questionnaires were returned, with response rates of 65% (UK), 74% (Germany), 63% (Sweden), 52% (Switzerland), and 46% (USA) for the validation study of PPE-15. Item total correlations recommended level of 0.3 (Spearman correlation) was achieved for all items for the UK (0.42–0.54), Switzerland (0.36–0.49), and Germany (0.34–0.58). However, one problem score fell below this criterion in Sweden and the USA: question 8 ('Doctors sometimes talked as if I wasn't there') achieved a correlation of 0.23 for Sweden and 0.25 for the USA. All other correlations exceeded the criterion of 0.3 (Sweden 0.32–0.48; USA 0.42–0.57). Removal of the item did not substantially increase reliability, and it also has high face validity as an important aspect of patient care, therefore this item was retained in the final measure. The PPE-15 index was highly correlated with the total number of items selected as 'problems'

on the original measure [correlations ranged from 0.93 ($P < 0.001$) for Sweden to 0.95 ($P < 0.001$) for the UK, Switzerland, Germany, and the USA] [342]. Although the PPE-15 was developed for use by doctors, the questions are generic and could be easily adapted to be used by other health professionals. It takes up to 10 minutes to complete.

d. **Consultation and Relational Empathy (CARE) Measure**: The CARE Measure is a 10-item person-centred process measure that measures the amount of empathy that a patient feels they have received during consultation [343]. The CARE Measure has been rigorously developed, tested and validated for use by most health professionals in adult out-patients. The initial version strongly correlated (r = 0.85) with the Reynolds empathy measure (RES) [344] and the Barrett-Lennard empathy subscale (BLESS) [345] (r = 0.63), however, the skewed distribution was high (skew 1.879, kurtosis 3.563). Interview study with 20 patients, GPs and expert researchers led to the revision of the initial version. The revised version of the CARE measure also strongly correlated with the empathy measures (r = 0.84 vs. RES and r = 0.77 vs. BLESS) however, the skewed distribution was low (skew 0.634, kurtosis 0.067). The internal reliability at this stage was high (Cronbach's alpha 0.92). Interview study with 13 patients led to a minor revision. The final version of the CARE measure proved validity with the other empathy measures (r = 0.85 vs. RES and r = 0.84 vs. BLESS) and face validity with 10 patients in an interview study [343]. Participants complete the measure after consultation in their own time and takes up to 10 minutes to complete.

e. **Positive Outcomes HIV PROM**: Recently developed at the Cicely Saunders Institute (2018), Positive Outcomes is a 23-item patient-centred PROM that reflects the range of outcomes relevant for PLWHA across six domains: physical, cognitive, psychological, social, welfare and information needs [346]. The data on the psychometric properties of this person-centred measure is unpublished however a discussion with the authors revealed that it meets the criteria for COSMIN properties [347].

The APCA POS, MOS-HIV and Positive Outcomes have been chosen to measure physical, psychological, social and spiritual wellbeing among PLWHA; and the CARE Measure and PPE-15 were chosen to measure the processes involved in care delivery.

Intervention and training content design

Following the expert panel recommendation to adopt palliative care skills to inform the intervention training content for HCP, the researcher selected and adopted existing palliative care resources including those used during the TOP Care trial [320]; African Palliative Care Association training resources [348]; and the palliative care training manual and tool kit [107, 349]. These resources were used in conjunction with the PCC theory and the qualitative data to draft the intervention training content (APPENDIX M) and the holistic assessment tool (APPENDIX N). The holistic assessment tool used in the TOP Care trial was modified and adapted for this intervention because it captured most of the PCC care domains described by PLWHA in the qualitative data. The training content was also developed to reflect the content of the holistic assessment tool and incorporating the qualitative data from stakeholders. A care plan (APPENDIX O) was developed and mirrored the domains of PCC needs identified, the holistic assessment tool as well as the training content. This ensured that the content of these documents developed from the above resources mapped onto the qualitative data, the PCC theory and most importantly the process and outcome measures selected for the intervention. The content of training, care plan and the holistic assessment tool draft were circulated among the expert panel members via email for feedback and review before final draft was concluded.

At this stage, details on the training content, number and duration of sessions to be attended by HCP, number of intervention appointments (dose) and duration of the intervention for PLWHA were concluded in the draft. The researcher also clarified the conditions and resources required to implement the intervention successfully and the related risks and assumptions. For instance, the availability of HCP for training and the cooperation of the clinic leads in allowing time for the intervention training and delivery. It was also anticipated that there could be potential unintended effects of the intervention, this anticipation informed the researcher to be prepared to minimise any harmful effects that could arise. Some of these effects have been classified as direct, psychological, group/social, opportunity and equity [350].

Step (v): Feasibility testing and refining the intervention - The final stage of the intervention development was to test the content and processes incorporated in the logic model. This final stage involved feasibility testing procedure (including testing methods for their acceptability and feasibility), estimating the likely rates of recruitment and retention of participants and the determination of appropriate sample sizes for the evaluation studies [178]. This Feasibility stage also aimed to address all the uncertainties identified in the Development stage (see section **3.12**, Phase 3: thesis objective 5 for detailed method).

3.12 Phase 3: Thesis objective 5

(MRC "Feasibility stage")

To deliver and test the feasibility of a cluster RCT of the intervention in terms of recruitment, retention, intervention delivery, estimate of potential effect and to appraise measures.

The research questions linked to thesis objective 5 are:

What is the feasibility of recruitment and retention of participants, and the potential effect size of the intervention?

What is the acceptability and fidelity of delivering the intervention among PLWHA and HCP?

How does the experience of the intervention and the process of delivering it help to refine the intervention?

3.12.1 Feasibility trial registration

This feasibility trial was registered on the ISRCTN registry with study ID ISRCTN13630241.

3.12.2 Feasibility outcomes

The primary outcomes for this feasibility cluster RCT are:

1. Recruitment rate
2. Retention rate

Secondary outcomes include:

1. Fidelity of the intervention training and delivery
2. Intervention delivery and acceptability, experience of the intervention and processes/ mechanisms of delivery
3. Estimate of potential effect size

3.12.3 Feasibility studies

Feasibility studies are very important in trial preparation, especially in planning evaluation of complex interventions [176]. In order to allocate resources for a future trial with the optimal chance of effective delivery, it is crucial to determine feasibility of recruitment, retention and intervention delivery [351]. Feasibility studies are “pieces of research done before a main study in order to answer the question ‘can this study be done?’’ They are “used to estimate important parameters that are needed to design the main study” [352]. The objectives of this feasibility study as outlined above is to deliver the newly developed person-centred intervention and to determine rates of recruitment and retention of participants, estimate the potential effect size and to establish acceptability and fidelity (extent to which the intervention was delivered as intended). Achievement of these objectives will determine whether the intervention can be implemented, could be evaluated in a trial, could be potentially effective and therefore warrant a future definitive trial [353]. By design, this feasibility cluster randomised controlled trial (cRCT) involved quantitative outcome data collection with a post-trial qualitative exit interview.

3.12.4 Quantitative component of the feasibility trial

3.12.4.1 Study design

A parallel group design with an allocation ratio of 1:1 was used for this feasibility cluster randomized controlled trial (cRCT) and reported in accordance with the CONSORT extension to randomised pilot and feasibility trials [354].

A cluster RCT was chosen for this study, which involves the allocation of groups of subjects (PLWHA) to different treatments arms [355, 356] rather than individual randomisation, in order to reduce/ minimise treatment ‘contamination’ [357] between the intervention and control arms (see Figure 11 for the feasibility cRCT flow diagram). Contamination of the control arm could reduce the estimate of the effect size of the intervention in a full trial; and this reduction could result in a type II error (rejection of an effective intervention as ineffective as the observed effect size will neither be statistically nor clinically significant) [358]. A cluster RCT is appropriate for this intervention as it involved training and mentoring of HCP to implement a new care approach, which would be generally acceptable than randomisation at the individual level [359]. Also, cRCT allowed for the assessment of the direct and indirect effects of intervention which provided a measure of the overall effect of implementing intervention in HIV population.

3.12.4.1.1 Measures to check for contamination

The researcher did not anticipate any contamination between the two clusters as the shortest and longest drive time distance between the clusters is about 6.2 and 8.6kilometers respectively as indicated in Figure 9 in section **3.6.1.1.** However, in order to guard against any form of contamination, participants were asked to notify the researcher or the HCP if between their last appointment they fell ill and have had to access medical services at another clinic other than their respective HIV clinics. The researcher also asked each participant about attendance to other clinics during outcome data collection.

3.12.4.2 Inclusion criteria

Refer to section **3.8.1.1** for inclusion criteria.

3.12.4.3 Setting

This feasibility cRCT was conducted in two community clinics in Ghana. Location of the two clinics used for the feasibility testing is shown in Figure 9, and clinic details have been described in section **3.6.1.**

3.12.4.4 Sample size

As this is a feasibility study, a formal power calculation based on detecting evidence for effectiveness was not conducted. In order to determine feasibility of recruitment to inform a future definitive trial, a sample size of 30 has been recommended to estimate a parameter such as a standard deviation for the calculation of sample size [360]. Therefore, a total of 60 participants were recruited across the two clusters in a ratio of 1:1, that is n=30 per clinic to participate in the feasibility cluster trial.

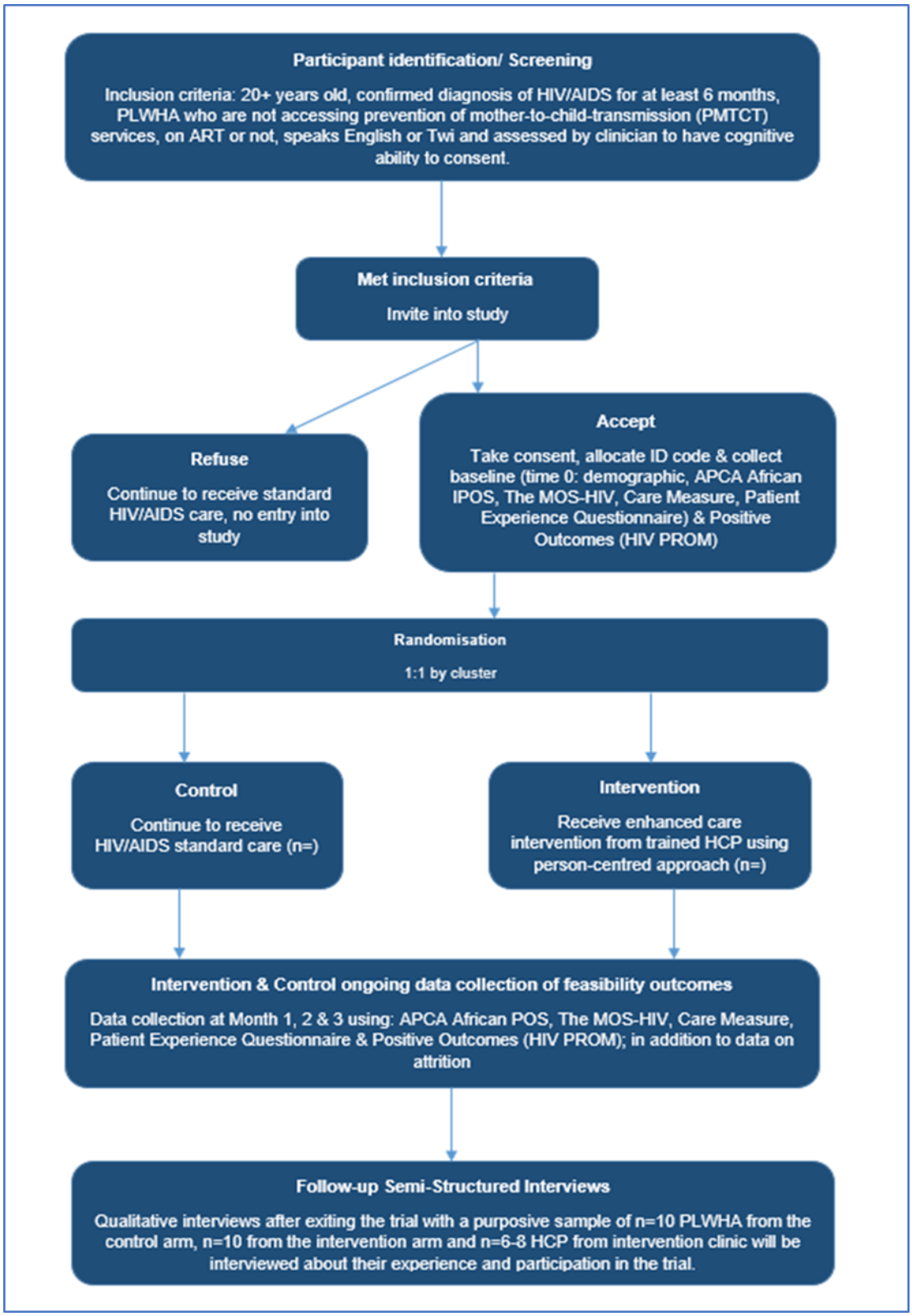


Figure 11: Feasibility cRCT flow diagram

3.12.4.5 Participant identification, consent and recruitment

Patients were initially approached by their HCP about the study, those who expressed interest in taking part in the study had their details passed on to the researcher (MA-O). The researcher then approached these patients, screened and assessed their eligibility for recruitment. Participants who met the inclusion criteria were taken through the information and consent process (APPENDIX P) in a separate private space, respecting the patient flow of the clinic. Participants who were willing to take part in the study provided written consent (APPENDIX Q) either by signature or thumb print. Participants were offered a minimum of 24 hours to consider participation in the study, after which consent was taken. Participants were allocated unique identifying numbers to protect their privacy. Detailed records of screening and recruitment were documented (APPENDIX R) and used in determining recruitment and consent rates of participants.

3.12.4.6 Baseline data collection

Baseline data were collected at the two study sites once participants provided written consent and prior to randomisation. Demographic questionnaire was used to collect demographic data on gender, age, partner status, number of children, number of financial dependents, level of education among others. In addition to this, the selected process and outcome measures for this feasibility cRCT were also used to collect participants baseline data before the two sites were randomised.

3.12.5 Randomisation

After providing consent and baseline data collection, the two clinics were allocated to 'Control' or 'Intervention' by independent off-site statistician conducting computerised randomisation. Clinic 1 was allocated to the control arm and clinic 2 was allocated to the intervention arm. The control arm continued to deliver Standard HIV Care (SHC) throughout the trial, and the intervention arm had their HCP trained to deliver the intervention.

3.12.5.1 Control arm

Standard HIV care (SHC) was selected as the control arm in order to assess the potential impact of the intervention as compared to existing practices in HIV clinics. Participants in the control arm continued to receive SHC provided by HCP who have had no exposure to the intervention. In

Ghana, SHC generally consists of one-monthly, two-monthly or three-monthly clinical appointments depending on when PLWHA started ART or their adherence status. PLWHA who started ART treatment within the last six months usually fall within the one-monthly or two-monthly appointments depending on their adherence status, and those who have consistent records of adherence have the three-monthly appointments. Patients may attend the clinic for repeat prescription of ART only, referrals to ART adherence support, nutrition support or may request more frequent appointments if they experience specific problems.

At the control arm, in line with the clinic protocols, PLWHA initially attend the clinic for ART repeat prescriptions on a monthly, two or three-monthly basis depending on how long they have been on ART, and their adherence history. However, for the purpose of this study, all participants recruited into the study were scheduled to attend their appointments once every month for the duration of the study irrespective of their regular clinic appointments, in order to assess outcomes for both arms on a monthly basis so that any difference cannot be attributed to additional appointments.

3.12.5.2 Intervention arm

The newly developed community-based enhanced care intervention (CECI) was delivered by HCP in the intervention arm who were trained on CECI components and tools in order to equip them to deliver CECI according to protocol.

3.12.5.3 HCP training on the CECI intervention

HCP in the intervention arm received training on the CECI delivered by the researcher (MA-O). This training was divided into three main sessions namely: person- centred communication and holistic assessment; psychological and social wellbeing; and physical and spiritual wellbeing (see APPENDIX M). Among the topics discussed under the three main sessions included communication, the holistic approach, quality of life, intimacy and sexuality, psychosocial assessment and management, pain assessment and management, the different aspects of spirituality demonstrated using the HOPE checklist, cultural issues, teamwork, counselling, the importance of holistic assessment, how to complete assessment tools and documentation. HCP were provided with copies of the holistic assessment tool and copies of care plan during the training, which were used to practice holistic assessment and collaborative care planning on their colleagues.

The training lasted two hours per day for three days, and each training session consisted of PowerPoint presentation, discussion and a role play acted by selected HCP to demonstrate what had been taught. Of the two hours allocated to each training session, one hour was dedicated to the discussion and PowerPoint presentation, and the remaining hour was dedicated towards the role play (see Figures 12 for CECI training session).

Figure 12: CECI training underway

Certificates (APPENDIX S) were awarded to HCP who completed all three training sessions. In addition to the certificates, daily refreshments were provided to HCP after each training day.

MA-O was mentored by Dr Edwina Opare-Lokko, a local palliative care lead, who also reviewed the content of PowerPoint slides on the training before the training commenced (see Figure 13 for the diagram on the intervention training).

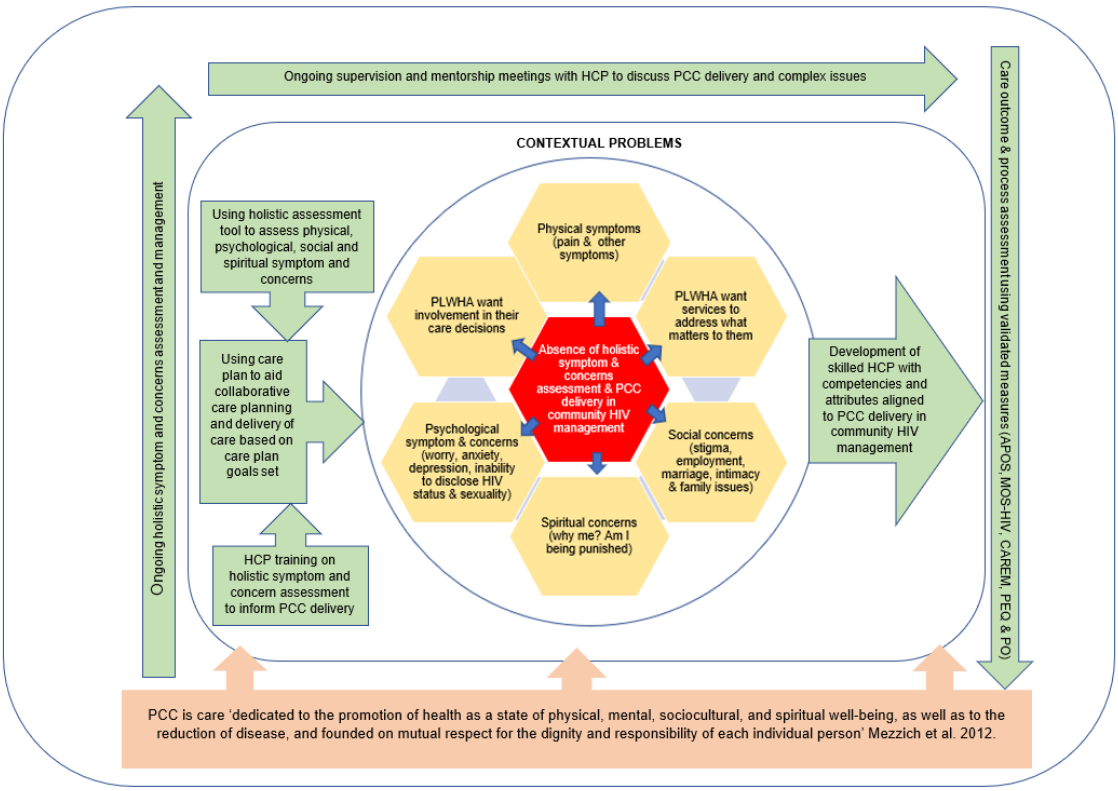


Figure 13: Diagram on intervention training

3.12.5.4 Holistic assessment tool and care planning

In the intervention arm, HCP holistically assessed PLWHA using the holistic assessment tool which assesses the domains of physical, psychological, social and spiritual wellbeing, including family, economic and emotional wellbeing. This holistic assessment tool was developed by drawing on tools and models used in sub Saharan Africa, which has been adapted for use in this study. PLWHA were assessed on current and anticipated care, symptoms and concerns were discussed, and an action plan agreed, leading to collaborative individualised care planning. The care plan aimed to provide quality comprehensive person-centred assessment with clear action plan on management. Where appropriate, PLWHA requiring services provided outside the clinic jurisdiction were referred after HCP communicated with providers of these services about the need for patient referral. Every clinical assessment item is being covered at each visit, with a particular focus on the problems identified at previous clinic visits. In order to track PLWHA progress during the trial, an ongoing summary record was kept highlighting areas of concern. This record is a summary document that was used to monitor PLWHA progress and to ensure chronic problem follow up. Predominantly, this summary record was used to document problems and concerns identified by the HCP and PLWHA during assessment and the action plan agreed and

subsequently revised on PLWHAs' progress or deterioration. The holistic assessment tool was designed as a prompt to ensure that assessment of PLWHA is holistic.

3.12.5.5 Mentorship for HCP and CECI supervision meetings

MA-O provided two-weekly mentorship and supervision meeting with HCP after the intervention training until the study closed. At these meetings, issues or challenges encountered during the delivery of the CECI, issues regarding the assessment tool, assessment and management of symptoms and concerns were discussed. Also, all PLWHA assessed during the week were discussed, case notes reviewed, and decisions appraised. The support meeting sessions also involved discussions around how PLWHAs' concerns were assessed, documented and reported on the assessment form in order to ensure that HCP were complying with the details on the assessment tool. HCP were asked about their experiences of using the holistic assessment tool, how they were completed and whether the assessment tools were partly or fully completed. MA-O took time to address the four domains of assessment for example, pain assessment (physical): and asked HCP how they assessed pain during the week; and if there were any challenges regarding pain assessment, HCP were taken through pain assessment to ensure that they were conversant with it. This process was followed for the various domains of assessments to ensure the completeness of the holistic assessment tool (see Figure 14 for mentorship and supervision meeting).

As part of this supportive meetings, MA-O also discussed with HCP, complex issues they encountered and felt unable to manage, for example, complex cases of psychosocial issues or pain, and these were referred appropriately. Clinical decisions made were jointly reviewed and discussed with HCP, this encouraged problem solving and skill development. MA-O also encouraged HCP to be reflexive about the care they were providing, how it impacted on them emotionally or stressfully and how they had managed this.

Figure 14: CECI supervision meeting underway

Step (vi): Collecting enough evidence to justify rigorous evaluation/ implementation

3.12.5.6 Prespecified criteria used to judge how to proceed with future definitive trial

Following Avery et al. [361] recommendation on specifying progression criteria for feasibility studies, these criteria were set for this feasibility trial for progression to a definitive cRCT :

1. Recruitment of 30 PLWHA within 8 weeks for each cluster
2. Retention of 80% of the total sample at T3 follow up
3. Establish intervention acceptability

3.12.5.7 Assessments to facilitate estimation of recruitment and retention rates

Three specific questions were asked in relation to thesis objective 5 (see the feasibility cRCT in section **3.12)**. The specific assessments recorded and used to address the first question, which also focused on the primary outcome of the study include:

i. % of eligible participants

ii. % of participants approached and screened

iii. % of participant that meet the inclusion criteria

iv. % of participants that consented and entered the trial

v. % of participants who declined participation

vi. % of participants that were present at each time point of data collection.

3.12.5.8 Data collection timepoints for the estimation of potential effect size of CECI

Data was collected monthly over three months after baseline data collection and training of HCP on CECI delivery (see Table 10). A participant pack was allocated to each participant, which was stored securely in the locked cabinet within the clinics. Each set of outcome measures (APPENDIX T) were colour coded to distinguish each month of data collection and different colour coding of outcome measures were presented to participants at each visit to facilitate progress monitoring. Participants had the freedom to choose whether to conduct the interviews in Twi or English or both languages. MA-O contacted participants who failed to attend an appointment and reminded them to attend. A two-week window was allowed after missing a scheduled appointment, after which non-attendance was recorded as missing. Data collection was recorded at four time points: baseline (T0), one month after intervention training was carried out (T1), two month post-intervention (T2), and three months post intervention (T3). At each time point, PLWHA received either the CECI or SHC before completing an outcome and process measures. Data was collected in the counselling room or a private space within the clinic when the counselling room was in use. The researcher on most occasions read aloud the questionnaires for participants to respond to, and responses were written in participants' respective packs in order to minimise the effect of varying levels of literacy in the sample.

The timeline comparing research activities at the two cluster sites from participant screening and recruitment through to the end of the post-trial qualitative interviews are reported in Table 11. As indicated in Table 11, HCP at the intervention site started delivering the intervention at week 3 when intervention training was completed at the end of week 2. However, study participants monthly appointments started at week 6. This was to allow HCP to get a sense of how the intervention was expected to be delivered before study participants start their first intervention appointment.

Table 10: Data collection and timepoints n=30

Both study arms	Baseline Includes Demographic data	Month 1	Month 2	Month 3	2-weeks after exit from trial
Quantitative data collection measures: APCA POS, MOS-HIV, CARE Measure, PPE-15 and Positive Outcomes	✓	✓	✓	✓	
Post-trial exit (interviews)					Sub-sample from both arms

Table 11: Detailed comparison of CECI and SHC to timelines and timing of CECI delivery

Timeline	**Intervention arm (CECI)**	**Control arm (SHC)**
Month 0 Consent, recruitment and baseline data collection	Participant recruitment into the study and baseline data collection using demographic questionnaires and baseline quantitative outcome data collection	
Randomisation		
Week 1	Informed will be delivering CECI and training scheduled	Informed will continue to deliver SHC
Week 2	CECI training started and completed in 3 days	-
Week 3	CECI delivery by HCP including twice-weekly supervision meetings	-
Week 4	CECI delivery by HCP including twice-weekly supervision meetings	-
Week 5	CECI delivery by HCP including twice-weekly supervision meetings	-
Month 1 Week 6	1st CECI appointment and repeat of baseline quantitative outcome data collection	1st SHC appointment and repeat of baseline quantitative outcome data collection
Week 7		
Week 8		
Week 9		
Month 2 Week 10	2nd CECI appointment and repeat of baseline quantitative outcome data collection	2nd SHC appointment and repeat of baseline quantitative outcome data collection
Week 11		
Week 12		
Week 13		
Month 3 Week 14	3rd CECI appointment and repeat of baseline quantitative outcome data collection	3rd SHC appointment and repeat of baseline quantitative outcome data collection
Week 15		
Week 16		
Week 17	End of feasibility trial	
Week 18		
Week 19		
Week 20	Post-trial exit qualitative interviews for purposefully sampled PLWHA participants from both clusters and only HCP who delivered the intervention.	

3.12.6 Qualitative component of the feasibility trial

3.12.6.1 Sampling and participant recruitment

PLWHA and HCP were recruited from the two clinics who participated in the feasibility cRCT. Both PLWHA in the intervention and control arms were approached to take part in the post-trial interviews, and HCP in the intervention arm only. This was important to further explore any potential therapeutic effects of participating in the trial beyond the potential benefits of the intervention as well as checking the acceptability of methods for control arm (what was it like being 'control'). Although Lowther et al [362] reported this type of effect as a methodological issue, due to the stigma attached to HIV disease and the social isolation experienced in this population [363], it was anticipated that taking part in a research where PLWHA regularly interact with the research team could potentially influence some effects, which are rarely examined. Participants were selected a minimum of two weeks after exiting the trial to allow them some time to reflect on their participation in the feasibility trial and how it may have affected them. The researcher contacted potential participants to enquire whether they would be interested and available to discuss their experience in the trial.

Purposive sampling was used to achieve maximum variation based on trial completion/non-completion, and age. All participants provided written informed consent (APPENDIX U) prior to interview.

3.12.6.2 Post-trial interview topic guide

A topic guide was developed and piloted for flow and comprehensiveness with one participant prior to data collection. The topic guide was structured chronologically to assess participants' perspective of their state of wellbeing before, during and after their participation in the trial, with different variations for participants in the control and intervention arms to reflect their different exposure.

3.12.6.3 Intervention

The specific topic guide developed for participants in the intervention (APPENDIX V) was used to ask about the participants' physical, emotional, social and spiritual wellbeing before the study began, and the effect on their ability to perform their activities of daily living, including work and other responsibilities. Participants were afterwards asked to describe their wellbeing during and after the trial had ended including their experience and thoughts on the most important aspect of

the intervention as well as their participation in the trial. Additionally, specific questions were asked about their experience of being recruited and data collection, receiving the intervention including components they found helpful or important to their wellbeing, which components they attributed improvement or deterioration to and the key differences they identified between the intervention and standard HIV care.

3.12.6.4 Control

Specific topic guide was developed for participants in the control arm (APPENDIX W) who participated only in the trial without receiving any aspect of the intervention. The topic guide explored participants' wellbeing in relation to their physical, psychological, social and spiritual wellbeing before, during and after participating in the trial. Specific questions were asked about how participating in the trial had affected or changed them in any way including their wellbeing in general. If change was reported, participants were asked the importance of this change taking place; and if no change reported, they were asked about what they needed to be happier. Participants were also asked about their experience of being recruited and data collection.

3.12.6.5 Data collection

Participants were contacted by the researcher about sharing their experience in the trial and those who consented, a date and time was agreed for the interview. On the day of the interview, participants were taken through the consent process including a discussion of the purpose of the interview, details on data protection and their right to privacy. Participants who were happy to proceed signed/ thumb printed the consent form prior to starting the interview. It was explained that the interview would be audio recorded and that if there were any questions that participants did not wish to answer, they could choose to omit or terminate the interview. In addition, it was explained that if the participant required a break or had any questions which they did not wish to be part of the interview, then the interview could be stopped. Participants who received the intervention were interviewed on their experience and receipt of the intervention, and participants in the control arm who received standard HIV care were also interviewed about their experience in the trial to further explore any potential therapeutic effects of participating in the trial beyond receipt of the intervention. HCP were interviewed about the intervention training, implementation, mentorship and support including fidelity monitoring.

Interviews were audio-digitally recorded. All interviews were conducted in participants' respective clinics including HCP. No participant objected to the interview being recorded nor did anyone ask for the recording to be stopped during the interview.

3.12.7 Data analysis

3.12.7.1 Quantitative component of the feasibility trial with descriptive analysis

This analysis reported data on the primary outcomes (estimated recruitment and retention rates) and secondary outcomes (missing data; mean difference of baseline (T0) compared to T1, T2 and T3 and 95% confidence interval using descriptive and inferential statistics). The potential effect size of CECI was estimated, and measures appraised. To estimate the effect size, analysis of covariates (ANCOVA) was conducted, with the outcome measures endpoint as the dependent variable and treatment centre as the fixed factor and baseline score, age, gender and CD4 count as covariates. Partial eta squared statistics were calculated using Cohen's d effect size references. A cross-sectional analysis of the baseline data T0 and the final time point T3 was conducted to assess change scores between T0 and T3; and change scores over T0, T1, T2 and T3. Analysis were conducted in SPSS v25 and reported in line with the CONSORT diagram for randomized pilot and feasibility trials [354].

3.12.7.2 Primary outcome – trial recruitment and retention

In terms of trial recruitment, the proportion of the target sample achieved including eligible participants, participants approached and screened, those meeting the inclusion criteria, those that consented and entered the trial and those who declined participation were used to estimate the recruitment rate. The CONSORT flow diagram shows the total number of potential participants screened, number meeting the eligibility criteria, reasons for excluding participants, number randomised, number missing appointments during the trial, and numbers retained at each timepoint (month 1, 2, and 3) in the trial follow-up. Descriptive statistics were presented for key feasibility outcomes, including recruitment rate achieved, participant eligibility rate in addition to retention rate of participants. Retention rates will be estimated using the proportion of participants recruited into the trial, and the proportion who remained until the end of the trial.

3.12.7.2.1 Baseline characteristics

Descriptive statistics were reported for the baseline and demographic characteristics of participants, by treatment arms (control and intervention), with means, standard deviations, or numbers and proportions reported as appropriate.

3.12.7.2.2 Adherence to the allocated treatment

The proportion of participants attending their appointments and adhering to their treatment in each arm including those attending 1, 2, or all 3 appointments were reported, if possible, reasons were given for any participant who missed an appointment both in the control and intervention arms. Fidelity checklist was used to appraise the intervention training, delivery and receipt of the intervention. The twice weekly meetings held with HCP throughout the intervention delivery were used to assess how the intervention was being delivered as well as addressed any challenges faced by HCP in the course of the intervention delivery.

3.12.7.3 Quantitative data with inferential analysis

3.12.7.3.1 Missing data

The analysis of missing data for this PhD considered number of items missing (single questions), number of units missing (missing all questionnaires for a time point), and the number of participants who may have exited the study early with reasons if available. Data collection was closely monitored allowing the researcher to document and account for reasons for missingness whenever possible in order to understand the extent of missing data in this dataset. Missing data were summarised by study arm and number of time points (see table 12).

Table 12: Template for reporting summary of missing data

Time points	Missing data type	Control	Intervention	Total control & intervention
Time 0	Missed single item Missed single questionnaire Missed interview Premature exit Deceased			
Time 1	Missed single item Missed single questionnaire Missed interview Premature exit Deceased			
Time 2	Missed single item Missed single questionnaire Missed interview Premature exit Deceased			

3.12.7.4 Secondary outcome – estimation of the potential effect size of the intervention

Symptoms and concerns were described for all timepoints (from baseline to final time point 3), and data plotted to show how scores changed for all three timepoints; however, the potential effectiveness was estimated using baseline and final timepoints scores.

Numbers and proportions of participants in both arms were reported, along with those who experienced more severe levels of symptom. Summary scores were tabulated and reported.

The analysis of change described the courses of symptoms and concerns over time. This was analysed for the whole study sample in both control and intervention arms in a 'forward' direction, from study entry to the final time point. Symptoms, concerns and experiences of care were likely to vary according to the treatment arms, and/or how often participants received the CECI. Summary statistics (mean and 95% confidence intervals) at each time point were reported for control and intervention arms. This demonstrated how symptoms, concerns, and care processes of the whole study population changed over time from study entry until participants exited from the trial.

Statistics of means and standard deviations were first calculated for all outcome measures used (APOS, MOSHIV, CARE Measure, PPE-15 and Positive Outcomes) for both the control and intervention arms from baseline to final timepoint. The mean scores for each of these measures at every timepoint were presented. For all the outcome measures, higher scores indicate lower symptoms burden, except for the APOS and Positive Outcomes where lower scores indicate higher symptom burden. The values for the mean scores, standard deviations, range, and the

size of the sample from which these summary statistics were derived are presented at each time point. One of the secondary outcomes for this feasibility trial was to estimate the potential effect size of the intervention. Consequently, an exploratory analysis was conducted to estimate the potential effect size of the intervention. This was done using ANCOVA using the outcome measures endpoint as the dependent variable, and treatment centre as the fixed factor and baseline scores, age, gender and CD4 count as covariates. Before the ANCOVA was conducted, normality test was conducted to check whether data was normally distributed, however, no significant outlier assumptions were conducted. Group difference estimates and associated confidence intervals were reported.

For outcome data, data completeness was measured at each timepoint for both the intervention and control arms, and results plotted to check for flooring and ceiling effects (to guide and inform primary outcome selection). Data completeness was reported and means/ standard deviations or medians and IQR (depending on data normality/symmetry of distribution) plotted for each timepoint.

3.12.7.5 Methods for handling multiple comparisons

No adjustment for multiple comparisons was undertaken as this was a feasibility study and therefore not powered to test for efficacy based on a specified outcome. Consequently, caution should be applied regarding the interpretation of inferences in group differences on secondary outcomes.

3.12.7.6 Qualitative analysis

Digital recordings of the post-trial interviews were transcribed verbatim and analysed using thematic analysis [269]. MA-O read transcripts to familiarise with data, before line by line coding was done to generate an initial coding framework. Three independent researchers (SE, LB, LC) reviewed six randomly selected transcripts, performed line by line coding of each individual transcript using the initial framework generated by MA-O, in order to develop a mutually agreeable coding framework. These researchers (MA-O, SE, LB, LC) met and agreed on the coding framework through discussion. This unified coding framework was applied to both PLWHA and HCP data sets. QSR NVivo 12 was used to assist data management and analysis.

See section **3.8.2**. for detailed steps of thematic analysis.

3.12.7.7 Data integration for thesis objective 5 (mixed methods feasibility cRCT)

Findings from the analysis of each data set in a mixed methods study can be integrated at data collection, analysis or data interpretation [205]. For this thesis, findings were integrated at the data interpretation stage (after the quantitative and qualitative components of the feasibility cRCT were analysed separately). Quantitative data analysis findings were used to interrogate the qualitative data and vice versa in order to address the secondary outcomes on CECI delivery and acceptability. The findings from the quantitative and qualitative analysis for thesis objective 5 were then presented and discussed, highlighting the qualitative explanation for findings from the quantitative analysis, and any incongruence or convergence in findings. First, the components of care delivered as part of CECI and how they differed from SHC were described. Post-cRCT qualitative data analysed thematically identified active ingredients of CECI and their mechanism of action and therapeutic aspects and processes attributed to study participation. PLWHA were asked directly in the interviews, what they attributed any change in their health status to, and how this attributed aspect might have an effect in the light of the quantitative results. This data was used as a starting point to identify any possible active ingredients of the intervention, with the rest of the interview data also examined.

3.12.8 Rigour and data quality

Throughout the conduct of the study, Skype calls (remote supervision) were held between the researcher and supervisors (RH and KB) a minimum of once every two weeks; including a face to face or telephone call with a mentor (EO-L) based in Ghana at least once a week. During these calls the researcher updated RH, KB and EO-L on number of participants screened, recruited and exited at different time points and discussed any matters arising.

The researcher was always present at the study sites and recorded recruitment data for each days' screening activities and sent copies to supervisors periodically including the daily and weekly totals of numbers of participants screened, eligible, recruited and consented. When recruitment was completed, RH and KB were informed before randomisation of the sites was conducted.

Progress on participants attending the data collection appointments were monitored daily and follow-up calls were made to participants who failed to attend appointments and were reminded to attend, and missing values were recorded two weeks after a participant failed to attend an

appointment. In so doing, the quality of the data was maintained, and the amount of avoidable missing data was reduced.

There was a distress protocol which was employed if a participant became distressed during data collection. Participants were made aware that if the researcher become concerned about their welfare (i.e. suicidal thoughts or abuse disclosures), their consent would be sought first before referring them to the clinic lead for appropriate support.

3.12.9 Feasibility criteria for progressing to a definitive trial

Although a variety of progression criteria may be used to assess the probable success of a definitive trial, the three predominating criteria include: trial recruitment, protocol adherence and outcome data [361]. Trial recruitment has been the main focus of progression criteria and has been considered the highest priority for both researchers and funders [364-368]. Therefore in this feasibility trial, % of participants approached and screened [369], % of participant that met the eligibility criteria [369], % of participants that consented, randomised and entered the trial [369, 370], % of participants that were present at each time point (T1, T2 & T3) of data collection after the CECI commenced and % of total clinic population eligible were recorded for the estimation of recruitment and retention rates. Therefore, the pre-existing data from these clinics in the quantitative component of the feasibility trial: the number of patients seen daily and the available data on the number of eligible patients in the clinic population, was used to inform a progression criterion on recruitment for this feasibility trial.

For the purpose of this study, the second progression criterion was a focus on protocol adherence for which assessment could include all procedures outlined in the protocol [371]. In this study, the focus of protocol adherence has been on the CECI and trial procedures. 'Cross-over' is one of the types of non-adherence that could occur [372] which is participants not receiving their allocated intervention but rather an alternative trial intervention not allocated to them. Cross-over causes the study arms to be more similar, reducing the power of the study and a smaller difference between the overlapping arms than expected [357, 373].

Another progression criterion was monitoring the completeness and quality of outcome data during the feasibility trial, which provided a valuable opportunity to identify any issues that could be amended to improve the conduct of data collection in a definitive trial. Each participant was expected to contribute complete data at predetermined time points, as outlined in the protocol

however, missing or inadequate data are inevitable, resulting in some participants not being included in the final outcome assessment. Among the reasons for missing or inadequate data include attrition, loss to follow-up, problems with the feasibility or acceptability of the outcome assessment protocol, or the issues with the outcome measure themselves. The amount of missing data can have important implications for the trial's required sample size. Sometimes, the available data may be of poor quality due to partly completed patient-reported outcome measure or data not collected promptly resulting in only a small percentage of usable data within the acceptable timepoint. Therefore, assessing completeness of outcome data to report with the progression criteria could be useful in forming the focal point for progression criteria in some clinical settings. Following the traffic light system of green (go), amber (amend) and red (stop) recommended by Avery et al. [361], when specifying progression criteria for feasibility studies, these criteria were set for this feasibility trial for progression to a definitive RCT :

i. Recruitment of 30 PLWHA within 8 weeks for each cluster
ii. Retention of 80% of the total sample at T3 follow up
iii. Acceptability of the intervention, training manual, and the intervention components by PLWHA and HCP in the intervention arm only trial design.

3.12.9.1 Feasibility

Success of the feasibility trial was measured in terms of our a priori criteria stated above, and if necessary, refined methods by integrating the qualitative and quantitative data. If success criteria were met, refinements were aimed at improving the design.

3.12.9.2 Acceptability

CECI acceptability was assessed using findings from the post-cRCT qualitative interviews with PLWHA and HCP.

3.12.10 Measures put in place to protect against bias

The following steps were taken, and their feasibility and acceptability were examined to reduce the risk of bias in a definitive trial:

a. Randomisation to the trial arms were performed after recruitment, consent and baseline data collection was completed by an independent statistician who was not involved in the study.

b. Although contamination due to movement of PLWHA between sites allocated to the different trial arms was possible, we anticipated this was minimal and therefore had little impact.

c. In order to have a complete outcome and process data, every effort was made to obtain data from all participants who did not withdrew consent.

d. To prevent selective outcome reporting, a comprehensive analysis plan was developed for the feasibility cRCT before data analysis commenced.

3.12.11 Refining the intervention using the data generated and the logic model

Qualitative data analysis explored the acceptability of the intervention, the extent to which participants and HCP engaged with it, perceptions of how the intervention influenced HCP behaviour and contextual factors. The analyses tested the hypothesised causal pathways expressed in the logic model and the intervention's theory of change (PCC). This information is necessary to inform the study design of a future definitive trial by determining which elements of the intervention worked well for PCC behaviour change in HCP, how they delivered the intervention and what adjustments would be required for further development.

Chapter 4 Results 1. Phase 1 (thesis objective 1)

4.1 Systematic review

4.1.1 Study characteristics

This review was registered in PROSPERO - CRD42019127913.

The search retrieved 1,720 papers and hand searching yielded 9 additional papers as shown in the PRISMA flow diagram in Figure 15 [243]. Of the 1,393 papers screened, 1,352 were excluded, leaving 41 papers for full-text review. Of these, 36 papers were excluded as they did not meet the inclusion criteria. Five papers were retained for final analysis. A total of 327 PLWHA and 68 HCP participants were included in the five studies retained. Three studies were classified as pilot and feasibility studies [374-376]; one qualitative observational study [377]; and one randomised controlled trial (RCT) [320].

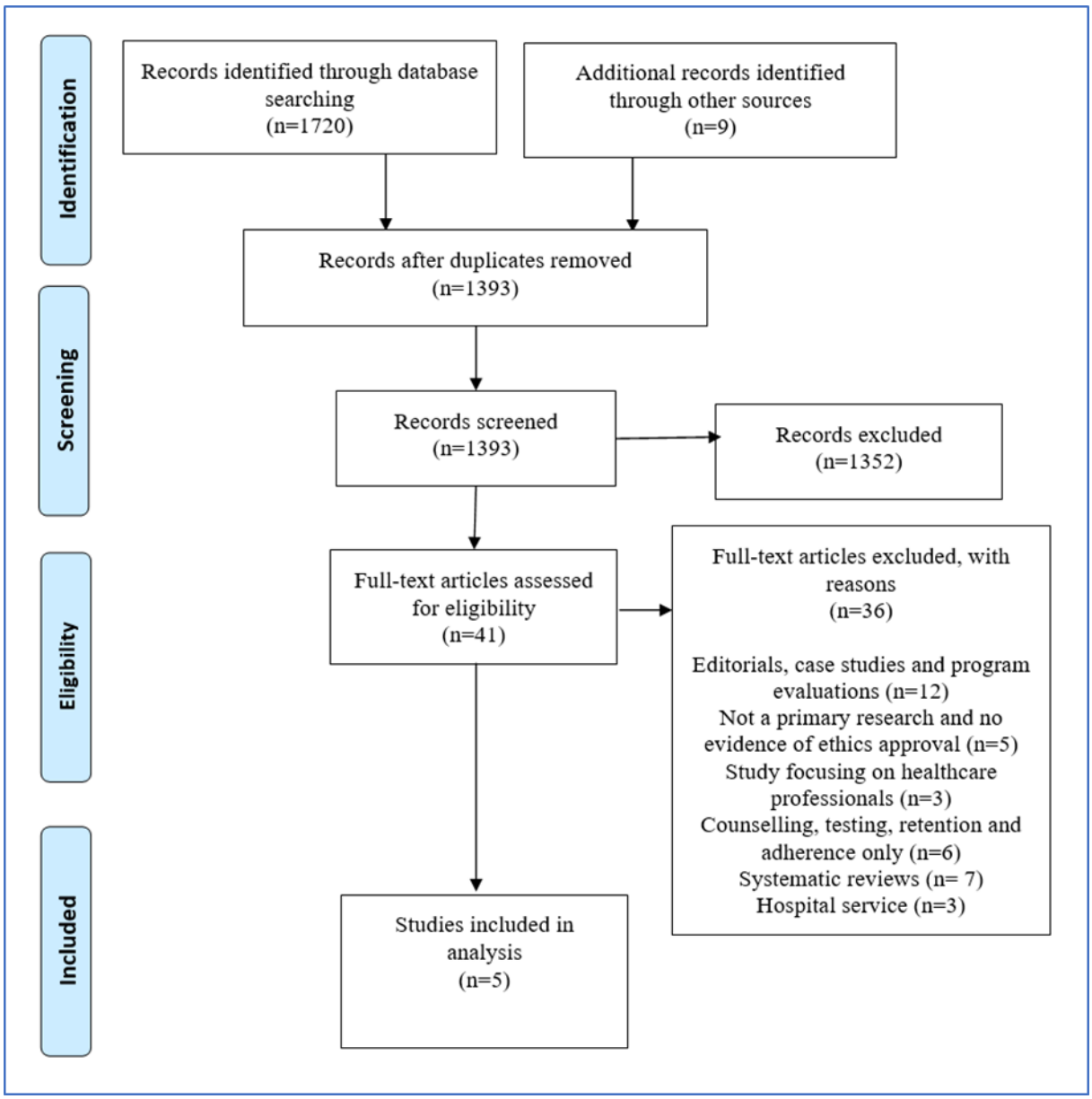


Figure 15: PRISMA flow diagram

Of the five studies retained, n=4 papers (80%) reported data from USA, a high-income country and n=1 paper (20%) reported data from Kenya, a lower-middle income country in line with World Bank classifications [378].

The median and range of the study design quality score of all retained studies are 0.7 and 0.6 – 0.9 respectively.

4.1.2 Person-centred care models

Components of care delivered were categorised according to Mezzich's definition (promotion of physical, mental, sociocultural, and spiritual well-being, alongside the reduction of disease [146],

see Table 13. Of the five studies retained, n=1 delivered two components, n=2 three components and n=2 delivered all four components.

Table 13: PCC components delivered in studies retained as mapped onto Mezzich's [146] domains

Study	Physical	Psychological	Social	Spiritual
Bendetson et al. [376]	✓	✓	✓	
Lowther et al. [320]	✓	✓	✓	✓
Morgan [374]	✓	✓	✓	✓
Robinson et al. [379]	✓	✓	✓	
Steward et al. [377]	✓	✓		

As demonstrated in Table 13, although all these studies claimed to deliver PCC, only two studies delivered all domains defined by Mezzich [146]. All five studies delivered care that addressed physical and psychological wellbeing, and 4 studies added social care, confirming previous reports that less attention has been given to spiritual wellbeing [155]. Details of data extracted from the retained studies can be seen in Table 14.

4.1.3 Details of PCC components delivered

(i) Physical wellbeing

All five (100%) studies delivered PCC domains that focused on physical wellbeing of PLWHA (see Table 13). These include medical treatment, selfcare, nutrition, pain other symptoms management [320, 374-377] and using tools like yoga, meditation and Reiki practice (Reiki is a Japanese technique for relaxing and reducing stress).

(ii) Psychological wellbeing

All five (100%) studies retained provided psychological care in addition to the physical care for PLWHA. The main forms of psychological care provided include counselling delivered through motivational interviewing, relationship building, and yoga, meditation and Reiki (as described above) [320, 374-377].

(iii) Social wellbeing

Four (80%) of the studies retained provided social care in addition to physical and psychological care to PLWHA [374, 376, 380]. Social care provided included support for developing meaningful relationships to reduce stigma, discrimination, social isolation and burden of disclosure; support

with legal issues, transportation, housing, the burden of caregiver and breadwinner roles as well as childcare issues.

(iv) Spiritual wellbeing

Two (40%) of the five studies retained included spiritual assessment [320] and provided spiritual support [320, 374] for PLWHA in addition to physical, psychological and social care. This spiritual care included supporting PLWHA to identify a reason to feel at peace, and to renew relationships with faith or other supernatural being considered important to them through meditation and Reiki Healing Circles.

Table 14: Data extraction table (n=5 papers)

Author/ Year/ Country/ Income status	***Quality Score***	***Study aim/ Design/ sample size***	***Care structure***	***Care processes***	***Person-centred care components***	***Outcomes/ measures used***	***Results and effectiveness***
Bendetson et al. [376], USA, High-income.	0.7	To evaluate the linkage to care specialist (LTC-S) intervention among those who were newly diagnosed of HIV in order to assess early emotional and cognitive reactions following a new HIV diagnosis, and their potential impact on linkage to care (LTC). Single group non-trial feasibility cross-sectional study, N=118.	Outpatient (participants were considered linked to care if they attended a medical visit with any HIV primary care provider within 3 months of diagnosis)	**Client-centred Linkage Intervention** *Phase 1*: mainly consists of client-centred, resiliency-based counselling and support, which starts immediately after a positive HIV test result with the aim of establishing a support and linkage plan. *Phase 2*: attempts to promote a sense of a responsive care system by demonstrating the flexibility and availability of the LTC-S through frequent meetings, phone calls text messages and/or email as individual needs dictates. LTC-S also focuses on helping clients develop or reinforce the concrete skills (planning ahead, making/ rescheduling appointments) that are required for successful engagement in care. *Phase 3*: is shaped mainly by client's readiness to engage in care, reflecting an efficient use of LTC-S and care team	i. Psychological care (counselling and support). ii. Physical care (addressing self-care goals and entering HIV medical care).	*Primary outcome:* Linkage to care, treated as a dichotomous (Yes/No) variable (Linkage to care is a face-to-face visit with an HIV medical provider within 3 months of diagnosis) *Secondary outcome:* Retention in care and viral suppression at retention, both treated as dichotomous (Yes/No) variables (Retention in care is defined as 2 HIV medical visits at least 3 months apart within a 12-month period. Viral suppression is having a viral load <200 copies per millilitre).	*Primary outcome:* Of the 118 recruited, 111 (94%) took an average of 25.5 days to link to care (range: 1-72days); the LTC-S spent an average of 2.1hours working with each participant (range: 0.5-5.2 hours). Interactions were mainly in-person meetings (mean: 1.8 per person) and phone conversation (mean: 2.7 per person). *Secondary outcome:* 102 participants (91.9%) of those linked were retained in care for the year following linkage. The development of individualised linkage and support plans through LTC-S encouraged autonomous and promoted a sense of personal control over self-care decisions. This client-centred, strength-based intervention was successful in linking 94% of enrolled participants in care. Results demonstrate that client-centred, resiliency-based LTC services can be seamlessly

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
				resources. For individuals who do not link initially but demonstrate interest in receiving care at the Center, the LTC-S introduces clients to care team members to help establish relationships. If any appointments are missed, the LTC-S intensified outreach to explore challenges and identify specific barriers to care. The LTC-S strategises with clients, providing referrals to any resources they may view as more pressing than HIV care at the time, and reschedules appointments when appropriate.		No validated measure was used.	integrated into an existing HIV testing program, thereby increasing the chances that newly diagnosed individuals will link to care.
Lowther et al. [320], Kenya, Lower-middle income.	0.9	To test the effectiveness of integrating palliative care into existing outpatient care for PLWHA on ART; RCT, longitudinal study N=120	Outpatient care in a community hospital	**Holistic patient-centred care** This intervention was delivered by two experienced nurses who received 2 weeks of fulltime palliative care (PC) training delivered by Kenyan experts from the Kenyan Hospice and Palliative Care Association (KHPCA). The experts used KHPCA's standard PC training programme with additional focus on HIV PC and quality of life in chronic disease. The training was didactic and delivered by nurses, doctors, and counsellors, with 4 days of	i. Physical (pain and symptom management, with nutrition services). ii. Psychological (not described), iii. Social (providing ethical and legal support and others not described) iv. Spiritual wellbeing (supporting PLWHA to understand the meaning of their	*Primary outcome*: 1-point change in pain score measured with APCA POS. *Secondary outcome*: i. 10-point change in quality of life (QoL) score (physical and psychological dimensions) measured with the MOS-HIV; ii. Psychological morbidity measured	*Primary outcome:* i. Pain - Control: [1.0 (IQR 0.0-2.0) at baseline to 5.0 (3.0-5.0)] at final timepoint; Intervention: [1.0 (0.0-2.0) at baseline to 4.5 (3.0-5.0) at final timepoint]. Compared to standard care, the intervention had no significant effect on pain (coefficient -0.01, 95% CI -0.36 to 0.34, p=0.95). *Secondary outcome:* i. MOS-HIV QoL - Physical health (coefficient 0.44, 95% CI 0.02 to 0.91, p=0.06); Mental health (coefficient 0.61, 95% CI 0.13 to 1.10, p=0.01).

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
				shadowing a PC clinician, who became their clinical mentor after the training. Topics included pain management, symptom management, nutrition, psychosocial and spiritual assessment and care, breaking bad news, ethical and legal issues, and bereavement. The nurses used a standardised multidimensional assessment and care planning instrument for all PLWHA allocated to the intervention to provide holistic PCC. The instrument was developed from existing assessment schedules from PC services across the region and systematically addressed physical, psychological, social, and spiritual wellbeing and patients' understanding of their illness and adherence to ART. Care plans were included to plan and review care against prioritised needs. The nurses had a weekly clinical support with their clinical PC mentor to review complex cases.	illness and to find peace)	with General Household Questionnaire-12 (GHQ-12); iii. Palliative care-related problems and concerns measured with APCA POS and ART adherence measured by asking questions about missed doses of ART and weather the timing was appropriate. Apart from ART adherence assessment, all measures used are validated.	ii.GHQ-12 Psychological morbidity (coefficient -0.50, 95% CI -0.97 to -0.03, p=0.04). iii. APCA POS (Palliative care related problems and concerns) total (0.69, 95% CI 0.26 TO 1.12, p=0.002): Symptoms (coefficient -0.05, 95% CI -0.39 to -0.29, p=0.78); Worry (coefficient -0.37, 95% CI -0.09 to 0.83, p=0.11); Ability to share feelings (coefficient 0.93, 95% CI 0.28 to 1.57, p=0.005); Feeling life worthwhile (coefficient 0.23 95% CI -0.48 to 0.94,p=0.52); Feeling at peace (coefficient 0.37 95% CI -0.18 to 0.93, p=0.19); Help & advise for family to plan for the future (coefficient 0.78 95% CI 0.28 to 1.28, p=0.002). Person-centred assessment and care delivered by trained nurses had positive effect on self-reported mental health related QoL and psychosocial wellbeing.
Morgan [374],	0.7	To examine the feasibility of an ongoing holistic	HIV/AIDS community service	**Practical holistic self-care tools** used to manage symptoms:	i. Physical (JourneyDance,	Physical, psychological,	i. All 10 participants either maintained or progressed to the next behavioural health treatment

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
USA, High-income.		wellness program in a residential facility for PLWHA; Single group non-trial feasibility cross-sectional study, N=10.	organisation providing medical respite, HIV case management, HIV testing and counselling, impatient chemical dependency treatment, mental health therapy, support groups, assisted living and independent housing	i. Use of yoga and JourneyDance to improve mood, perceived stress, and quality of life; ii. Use of meditation (a state of heightened mental awareness and inner peace) to promote mental, physical, and spiritual benefits; iii. Use of Reiki Healing Circles (a Japanese practice for relaxation) to reduce stress and may also promote physical, emotional, mental, and spiritual healing; iv. Use of Reflective Journaling (a guided questioning and restructuring strategies) to help PLWHA to examine their feelings and cognitions surrounding maladaptive health behaviours through interactive journaling binders.	Meditation, Reiki Healing Touch) ii. Psychological (Yoga, JourneyDance, Meditation, Reflective Journaling) iii. Social (Reflective Journaling and JourneyDance), iv. Spiritual wellbeing (Meditation, Reiki Healing Touch)	social and spiritual wellbeing Improvement in physical, psychological, social and spiritual wellbeing. No validated measure was used	level and no reported drug or alcohol relapse was noted during the 4-week program. ii. Survey responses from PLWHA consistently indicated a feeling of calm with more energy, physically stronger, sleeping better, more physically stable, and generally better equipped to selfcare. iii. PLWHA also expressed a feeling of patience, increased mental focus, and confidence in their ability to address everyday issues and the physical symptoms associated with HIV. iv. 3 of the 10 reflective journals were 100% completed. Others reported still working on their journals and intended to complete all the guided questions. All 10 PLWH agreed that the journal should be incorporated into future programs. v. 9 of the 10 PLWHA completed the Reiki Healing Circles practitioner training and received Level 1 practitioner certification. vi. 5 weeks post-program meeting held revealed three main themes: a) PLWHA want the holistic wellness program to be

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
							mandatory; b) PLWHA felt empowered to have acquired more tools to practically integrate into their lives and c) PLWHA requested that the holistic activities become part of an ongoing outpatient activity.
Robinson et al. [379], USA, High-income.	0.6	To describe nursing interventions provided to PLWHA in a home setting using palliative care framework; Single group pilot study using a cross-sectional design, Nurses n=8, PLWH n=26.	Home-based care	Care delivery with **palliative care** philosophy i. Nurses were instructed to audiotape a description of the intervention they provided in home visits right after he visit; ii. The principal investigator conducted an observation home visit, wrote and discussed every intervention observed with the nurse after each visit; iii. Sign and Symptom Checklist was used to determine whether PLWH were experiencing HIV-related symptoms “today” and if so, to rate the symptoms as mild, moderate or severe.	i. Physical (symptom assessment and management) ii. Psychological (allowing PLWHA to talk about their mood and missing their loved ones, ad about their declining health) iii. Social wellbeing (mitigating social isolation of being homebound)	*Outcomes:* i. Symptoms of PLWHA (physical and psychological) measured with Sign and Symptom Checklist for HIV (SSC-HIVrev); ii. Psychological (support was provided to PLWH regarding final arrangements towards the end of life); iii. Social/ emotional concerns (social isolation of being homebound which affected eating habit was addressed by buying client takeaway; and planning a marriage/ vacation	i. Top ten symptoms reported by PLWHA were: (a) numbness/ tingling of feet and toes (69.3%); (b) Muscle aches (61.5%); (c) Weakness (61.5%); (d) numbness and Tingling of legs (61.5%); (e) Fatigue (53.9%); (f) Painful joints (57.7%); (g) Thirst (53.8%); (h) Depression (50%); (i) Shortness of breath with activity (50%); and (j) difficulty concentrating (46.2%). ii. Improvement in psychological and social wellbeing were addressed using a qualitative approach

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
						trip. Although marriage did not happen, client still had a vacation with partner). SSC-HIVrev is validated	
Steward et al. [377], USA, High-income.	0.7	To examine provider and patient perspectives of the patient-centred medical home (PCMH) at five demonstration project sites to understand why the sites emphasise the implementation of PCMH components that did not require patient activation; Qualitative observational study; Providers n=60, PLWH n=53.	Outpatient primary care clinic	**Patient-centred** medical homes HCP relied on patient activation including expanded clinic hours, same day appointments, patient electronic health record portals to collaboratively develop and implement care plans	i. Physical (integrating medical and nonmedical case management) ii. Psychological (not described).	N/A	N=60 HCP and 53 PLWHA were interviewed. i. Both PLWHA and HCP spoke highly of patient-centred medical home's care coordination (new position) component, making it the endorsed mechanism of action; ii. PLWHA also spoke highly of team-based model of care making them able to see any of the team members without any hesitation; iii. PLWHA further reported their clinic utilisation was linked to patient-centred medical home's attributes on open communication as they were able to talk to their providers without holding back any information through email, phone calls or in person. iv. HCP also spoke highly of PLWHAs' perspectives on patient-centred medical home's impact on stigma and how it has elicited a

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
							need for creating trusting environments for PLWHA. v. Both HCP and PLWHA emphasised that trust was crucial in overcoming non-attendance to HIV clinics.

4.1.4 Using the Donabedian framework of healthcare quality

This review used the Donabedian framework structure, process and outcome components [381], to assess the quality of care delivered in the retained studies.

4.1.4.1 Care structure

Structure represented the physical setting where care was delivered including HCP who delivered the care. Three studies utilised outpatient services within primary and community clinics [320, 376, 377], and the remaining two studies delivered services in a home-based and residential facility (where PLWHA lived permanently) [374, 375]. Services provided for PLWHA within these care structures were delivered or led by trained HCP.

4.1.4.2 Care process

Process comprised the approaches used to deliver care, which was dependent on the care structures or mechanism and resources required to deliver care, bringing about result that impacted on patient outcomes. Care processes described by all studies included consultations, yoga, meditation and Reiki practice for medical treatment, adherence, selfcare, nutrition, fatigue, muscle aches, weakness, pain other symptoms assessment and management, (physical); counselling delivered through motivational interviewing, relationship building, and yoga, meditation and Reiki practice for depression, perceived stress and psychological distress (psychological) [320, 321, 375-377].

Those who provided social care also utilised client-centred communication and Reiki practice to develop meaningful relationships and provision of material support to mitigate against stigma and discrimination, social isolation, burden of disclosure, legal issues, transportation, housing, the burden of caregiving and breadwinner roles [320, 321, 375]. Moreover, those who provided spiritual care supported PLWHA through meditation and Reiki practice to identify a reason to feel at peace, and to renew relationships with faith or other supernatural being considered important to them [320, 321].

Authors also described linkage to care specialist (LTC-S): a licenced clinical social worker with experience in crisis counselling, developed a novel client-centred approach to linkage to care. The LTC-S draw on motivational interviews and strength-based case management techniques in addressing negative emotions (fear and stigma) surrounding new HIV diagnosis by seeking to redirect these natural reactions into productive health-seeking behaviours. LTC-S are flexible and

available through frequent meetings, phone calls text messages and/or email as individual needs dictates [376].

HCP were also trained to use a standardised multidimensional assessment and care planning instrument developed from existing assessment schedules from palliative care (PC) services across Africa and systematically assessed and addressed physical, psychological, social, and spiritual wellbeing, and PLWHAs' understanding of their illness and adherence to ART. Care plans were included to plan and review care against prioritised needs. The HCP had a weekly clinical support with their clinical PC mentor to review complex cases [320]. Additionally, practical holistic self-care tools including Yoga, JourneyDance, Meditation (a state of heightened mental awareness and inner peace), Reiki Healing Circles (a Japanese practice for relaxation) and Reflective Journaling (a guided questioning and restructuring strategies) were utilised in managing symptoms and concerns of PLWHA in the domains of psychological, physical, social and spiritual wellbeing [321].

A palliative care approach was also used to identify and manage physical and psychosocial symptoms including numbness/ tingling of feet and toes; muscle aches; weakness; numbness and tingling of legs; fatigue; painful joints; thirst; depression; shortness of breath with activity; and difficulty concentrating [375]. Furthermore, HCP promoted patient activation including expanded clinic hours, same day appointments, patient electronic health record portals to collaboratively develop and implement care plans [377].

4.1.4.3 Outcomes

Various outcomes were described including linkage to care, adherence, retention in care, viral suppression, and improvement in physical, psychological, social and spiritual wellbeing. Of these outcomes only one study used validated measures to measure care outcomes [320]. The most common outcomes assessed in these studies were adherence, retention in care, viral suppression, linkage to care and improvement in physical and psychological wellbeing [320, 321, 375-377]. The least outcomes assessed were social [320, 321, 375] and spiritual wellbeing [320, 321].

The client-centred linkage intervention process used was effective in linking n=111 (94%) newly diagnosed PLWHA to care within an average of 25.5 days and retained 91.9% of the sample linked. Linkage to care was described as a face-to-face visit with an HIV medical provider within

3 months of diagnosis; and retention in care described as two HIV medical visits at least 3 months apart within a 12-month period [376].

The HCP trained to use standardised multidimensional assessment and care planning [320], resulted in multidimensional outcomes measured with validated tools as follows: pain measured with APCA POS comparing a PCC intervention to standard care found no significant effect on pain (coefficient -0.01, 95% CI -0.36 to 0.34, p=0.95); physical health measured with MOS-HIV had no significant effect on physical health (coefficient 0.44, 95% CI 0.02 to 0.91, p=0.06) but was effective on mental health (coefficient 0.61, 95% CI 0.13 to 1.10, p=0.01). Furthermore, psychological morbidity measured with GHQ-12 was effective (coefficient -0.50, 95% CI -0.97 to -0.03, p=0.04). Also, concerns such as APCA POS worry (coefficient -0.37, 95% CI -0.09 to 0.83, p=0.11); ability to share feelings (coefficient 0.93, 95% CI 0.28 to 1.57, p=0.005); feeling life worthwhile (coefficient 0.23 95% CI -0.48 to 0.94, p=0.52); feeling at peace (coefficient 0.37 95% CI -0.18 to 0.93, p=0.19); help and advice for family to plan for the future (coefficient 0.78 95% CI 0.28 to 1.28, p=0.002) were all significantly effective on the wellbeing of PLWHA [320].

The use of practical holistic self-care tools including Yoga, JourneyDance, Meditation, Reiki Healing Circles and Reflective Journaling was reported to be effective in improving mood, perceived stress, quality of life in addition to promoting physical, emotional, mental, and spiritual healing in PLWHA, although these outcomes were not measured with validated tools [321]. Also, the palliative care approach used reported improvement in physical, psychological and social wellbeing [375]. Finally, patient activation process used especially attributes on open communication was effective in improving stigma and clinic utilisation, as PLWHA were able to talk to their providers through email, phone calls or in person without holding back any information [377].

4.1.5 Summary

This review highlights the lack of research evidence in terms of PCC components (physical, psychological, social and spiritual wellbeing) delivered alongside HIV clinical management in community settings. Findings also indicate that PCC interventions that focus on training HCP to holistically assess and manage clinical symptoms and concerns of PLWHA as part of the care delivery process, can improve outcomes including wellbeing and quality of life for PLWHA. Consequently, future plans for PCC intervention development should focus on training HCP to

identify and manage multidimensional needs of PLWHA, as well as explore context specific PCC components for PLWHA to inform future PCC interventions and policy recommendations that can translate into clinical practice.

Chapter 5 Results 2. Phases 2 (thesis objectives 2, 3 and 4)

5.1 Phase 2. Thesis objectives 2, 3 and 4: Qualitative interview

This section reports findings from the development phase qualitative interview study addressing thesis objectives two, three and four.

Thesis objective 2. To explore the views of PLWHA and healthcare professionals (HCP) about current HIV/AIDS care, its accessibility, and to determine which person-centred outcomes matter to PLWHA.

Thesis objective 3. To map the qualitative data from objective (2) onto the components of person-centred care theory to determine which components align with the theory and what additional components are required.

Thesis objective 4. To integrate findings from objectives 1-3, modelling the potential processes, outcomes, and mechanisms of action for the intervention.

Figure 16 indicates the phase of the MRC guidance that this section addressed.

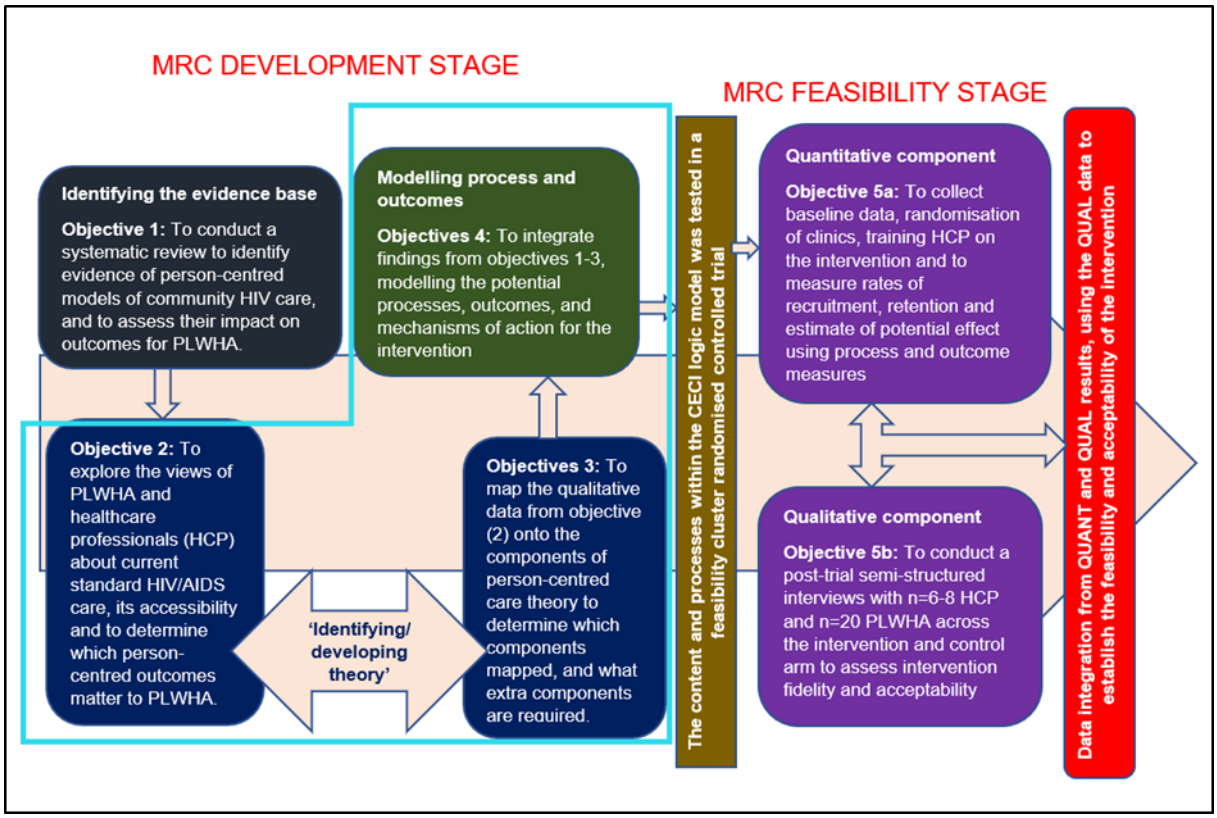


Figure 16: Qualitative intervention development stage of the MRC guidance

5.2 Thesis objective 2

To explore the views of PLWHA and healthcare professionals (HCP) about current standard HIV/AIDS care, its accessibility, and to determine which person-centred outcomes matter to PLWHA.

Research question

What are the views of PLWHA and HCP on current HIV care, its accessibility, and what person-centred outcomes matter to PLWHA?

5.2.1 Details of participants recruited for interviews

Fifty potential participants were approached across PLWHA and HCP participants of which n=11 declined to be interviewed resulting in a recruitment rate of 78% (with eligible PLWHA and HCP each achieving a recruitment rate of 69% and 100% respectively) See Table 15 for participant recruitment details.

Table 15: Interview participants recruitment details

	Potential participants approached		**Total**
Recruitment information	**PLWHA**	**HCP**	**PLWHA and HCP**
Number of potential participants approached	35	15	50
Number of potential participants declined to be interviewed	11	0	11
Main reasons for declining participation	➢ Lack of time ➢ Not interested	N/A	N/A
Total number recruited for interview	24	15	39
Interview recruitment rate	69%	100%	78%

Of the n=39 participants consented to be interviewed, n=24 were PLWHA and n=15 were HCP. All eligible HCP approached agreed to take part in the interviews and comprised doctors, nurses, pharmacists, counsellors, social worker, human resource managers, laboratory technicians and healthcare assistants (see Table 16 for participant characteristics).

Of the PLWHA sample interviewed, 50% were female and median age was 42.5 years (range 20 to 65). Median interview duration was 50 minutes (range 45 to 73 minutes). Likewise, the HCP sample interviewed had 53% female participants and a median age of 34 years (range 24 to 56). Median HCP interview duration was 45 minutes (range 40 to 67 minutes).

Table 16: Summary of participant characteristics n=39

PLWHA (n=24)	**n (%) Total**
Gender:	
Male	12 (50%)
Female	12 (50%)
Sexual orientation:	
Men who have sex with men	7 (29%)
Heterosexual	16 (67%)
Women who have sex with women	1 (4%)
Religion:	
Christian	13 (54%)
Muslim	4 (17%)
Traditional believer	7 (29%)
Relationship status:	
Single	9 (38%)
In relationship	15 (62%)
Age:	
Median (range)	42.5 (20-65)
Clinical:	
Median years since diagnosis	5.5 (6months -18 years)
PLWHA with comorbidities	16 (67%)
HCP (n=15)	
Median Age	34 (24-56)
Profession:	
Doctor	2 (13%)
Nurse	5 (33%)
Pharmacist	2 (13%)
Counsellor	2 (13%)
Social worker	1 (7%)
Human resource manager	1 (7%)
Laboratory technician	1 (7%)
Healthcare assistant	1 (7%)
Gender:	
Male	7 (47%)
Female	8 (53%)
Median years delivering HIV care	2 (6months – 14 years)

5.2.2 Achievement of purposive sampling frame for PLWHA

The a priori purposive sampling frame used to guide the recruitment of PLWHA included gender, sexual orientation, ART status, years of HIV diagnosis, CD4 count, viral load, comorbidities, living situation and employment status. Of the n=24 PLWHA participants who took part in the interview, there were n=12 male and female. There was no transgender or any other gender identification. For sexual orientation, a sample of n=16 heterosexual people, and eight people from sexual minority groups (n=7 men who has sex with men (MSM) and n=1 woman who have sex with women (WSW)) were recruited. The researcher also recruited n=21 participants who were active on ART and n=3 who had defaulted, with years of HIV diagnosis ranging from 6 months to 18 years. Moreover, n=15 and n=10 participants' viral load and CD4 count records respectively could not be found (either these participants did not have money to enable them to have these tests done or the test results were not available at the time of the study). Furthermore, n=16 participants had comorbidities (with n=2 participants having two comorbidities), n=18 and n=22 lived alone and were in employment (which includes petty trading, receptionist and construction) respectively. Table 17 is a summary record of how the a priori sampling criteria was met.

Worthy of note is that 29% for this sample were MSM, highlighting the successful recruitment of this category of participants. In Ghana same sex relationships have not been legalised and those in same sex relationships face significant risks if they disclose their sexual orientation.

Table 17: Details of how the a priori sampling criteria were met

Priori sampling Criteria	**Sampling criteria met**				**Criteria not met**
Gender	Male n=12	Female n=12	Transgender n=0		Partially met
Sexual orientation	WSW n=1	MSM n=7	Bisexual n=0	Heterosexual n=16	Partially met
ART status	Active n=21	Defaulter n=3			Fully met
Years of diagnosis	6months to 18 years				Fully met
CD4 count (cells/mm^3)	1 to 1,500 cells/mm^3				Partially met
Viral load (copies/mL)	10,000 copies/mL to undetectable				Partially met
Comorbidities	N=16				Partially met
Living situation	Lives alone n=18	With others n=8			Fully met
In employment	Yes n=22	No n=2			Fully met

The above purposive sampling frame were not fully met as the researcher was not able to recruit any transgender or bisexual participants. Furthermore, it was not feasible to use CD4 and viral load as a sampling criterion as not all patients could afford to have these tests done, which is an important cultural/ Africa specific challenge of using these biomedical markers in sampling. See Table 18 and 19 for the details of sampling criteria recruited for PLWHA and details of HCP participants recruited respectively.

Table 18: Details of sampling criteria recruited n=24

ID	Age in years	Years of diagnosis	Gender (Male /female /transgender /other)	Sexual orientation	ART status (Active/ defaulter /not yet started)	Viral load (copies/mL)	CD4 count (mm^3)	Living situation (Lives alone/ with others)	Comorbidities	In employment (Yes/No)
QID1	52	8	Female	Heterosexual	Active	Missing	Missing	Lives alone	Diabetes	Yes
QID2	43	18	Female	Heterosexual	Active	Not det.	1454	with others	Hypertension	Yes
QID3	59	3	Female	Heterosexual	Active	Missing	Missing	with others	None	Yes
QID4	20	0.6	Male	MSM	Active	114579	500	Lives alone	None	No
QID5	36	4	Female	Heterosexual	Active	112298	890	Lives alone	Hypertension	Yes
QID6	35	2	Female	Heterosexual	Active	Missing	Missing	Lives alone	Diabetes	Yes
QID7	43	3	Male	Heterosexual	Active	117687	798	Lives alone	Diabetes & Hypertension	Yes
QID8	43	3	Female	Heterosexual	Active	35567	643	Lives alone	None	Yes
QID9	25	2	Male	MSM	Active	125643	345	Lives alone	None	Yes

ID	Age in years	Years of diagnosis	Gender (Male /female /transgender /other)	Sexual orientation	ART status (Active/ defaulter /not yet started)	Viral load (copies/mL)	CD4 count (mm^3)	Living situation (Lives alone/ with others)	Comorbidities	In employment (Yes/No)
QID10	35	12	Female	Heterosexual	Active	123211	174	with others	Diabetes	Yes
QID11	57	0.5	Female	Heterosexual	Active	Missing	Missing	Lives alone	Arthritis	Yes
QID12	36	1	Male	Heterosexual	Active	Missing	Missing	Lives alone	Hypertension	Yes
QID13	26	0.5	Male	MSM	Active	114465	576	Lives alone	None	Yes
QID14	32	3	Female	Heterosexual	Defaulted*	Missing	Missing	Lives alone	None	Yes
QID15	41	6	Female	Heterosexual	Active	Missing	Missing	Lives alone	Migraine	No
QID16	61	7	Male	Heterosexual	Active	Missing	Missing	Lives alone	Hypertension	Yes
QID17	42	6	Female	Heterosexual	Active	Missing	Missing	Lives alone	Diabetes	Yes
QID18	50	6	Male	Heterosexual	Active	Missing	Missing	with others	Hypertension & Diabetes	Yes
QID19	28	5	Male	MSM	Active	Missing	394	with others	Hepatitis	Yes
QID20	27	10	Male	MSM	Active	123455	786	Lives alone	None	Yes
QID21	61	17	Male	MSM	Defaulted*	Missing	234	Lives alone	Diabetes	Yes

ID	Age in years	Years of diagnosis	Gender (Male /female /transgender /other)	Sexual orientation	ART status (Active/ defaulter /not yet started)	Viral load (copies/mL)	CD4 count (mm^3)	Living situation (Lives alone/ with others)	Comorbidities	In employment (Yes/No)
QID22	64	7	Male	Heterosexual	Active	Missing	897	with others	Hypertension	Yes
QID23	65	10	Female	WSW	Defaulted*	Missing	975	Lives alone	None	Yes
QID24	56	13	Male	MSM	Active	Missing	997	Lives alone	Hypertension	Yes

*Default case is defined as missing two or more HIV clinical appointments

Table 19: Details of HCP participant sampled n=15

ID	Age	Gender	Role in clinic	Years of working in this clinic
SQID1	32	Male	Social worker	2
SQID2	38	Female	Nurse	6
SQID3	32	Female	Nurse	8
SQID4	46	Female	Doctor	14
SQID5	34	Male	Nurse	6
SQID6	56	Male	Counsellor	2
SQID7	37	Female	Human resource manager	0.5
SQID8	24	Female	Nurse	0.5
SQID9	32	Male	Laboratory technician	8
SQID10	33	Male	Counsellor	5
SQID11	25	Male	Healthcare assistant	0.8
SQID12	35	Female	Doctor	0.5
SQID13	32	Female	Nurse	2.5
SQID14	40	Male	Pharmacist	1
SQID15	42	Female	Pharmacist	2

5.2.3 The interview processes

This section presents how the researcher transitioned from clinical to research interviewing and using gentle probing to elicit sensitive information from participants.

5.2.3.1 Transition from clinical (nurse) to research interviewing

During the early interviews, the researcher had challenges of accepting the new “research” role as distinct from the “nurse” role. Particularly she struggled with putting aside the nurse role and the desire to counsel or offer help to participants. Having identified this challenge at onset of the interviews, the researcher critically reflected on her degree of comfort and preparedness to conduct the interviews. The searcher also discussed this challenge with her supervisors KB and RH, who helped the researcher to identify aspects of the interview that was challenging as well as acknowledging that while the researcher have clinical skills or experience that was related to the subject of enquiry, those experiences and skill could not be applied in the research interview in the same way that the insight sought would be used clinically.

This reality reflected the researchers’ underlying shift from being someone whose expertise was being sought (nurse), to someone who was an inquirer (the researcher) seeking out the

experience of PLWHA in order to better understand their symptoms and concerns. After this period of reflection and discussion with supervisors, the researcher applied lessons learnt from qualitative interview training sessions completed and the Research Methods and Statistics module attended. Consequently, the researcher adopted a different approach for subsequent interviews and throughout the whole study and data collection. This included refraining from counselling participants during interviews and where appropriate offered advice or counselling for any issues that were raised that made participants upset when the interview was over. Doing this for each interview gradually transitioned the researcher (nurse) into the actual role of being a qualitative researcher. This was done in order not to influence the information gathered during interview process. Achieving this balance was crucial in identifying the real care needs of PLWHA in order to develop appropriate interventions that would best address their needs rather than just offering support during the process of the interviews.

Although the interview process was emotionally draining and it took hard work to complete, the researcher experienced personal satisfaction from the sustained contact over time with these participants. The researcher felt a genuine pleasure in learning more about HIV/AIDS and the care experiences of PLWHA and felt privileged that participants felt able to open up about intensely personal issues.

5.2.3.2 Probing during interviews and participants' joy of being part of the interview

There were times when participants were reluctant to disclose their marital relationships and sexual orientation and their impact on their wellbeing, however on gentle and careful probing (Could you tell me a little more about that?, Could you give me an example of that?, When you say that, what gave you that impression, What exactly was it that you liked?, How did you respond when?, What did you feel when?, Why do you think this is important?, What effect did that have on you?, Did that help in any way? What makes you say that?, What was it about this that made you feel/ do/ decide to etc, How was that helpful/ unhelpful/ difficult?, Could you explain what you mean by...?, Before you said …. But you also say …. [highlighting contradiction], and What are the main feelings you're left with?) participants opened up and reveal their issues and concerns. Participants seemed motivated to take part in the interviews largely because they are rarely asked about their care and involvement in planning this care. A number of participants expressed their happiness of being part of the interviews and the fact that they have been considered worthy to contribute to their care.

5.2.4 Thematic framework

Three main themes emerged from the qualitative data:

Theme 1 - Care structures are not currently built around the person;

Theme 2 - Priority outcomes and components of PCC; and

Theme 3 - Re-engineering HIV care to be more person-centred.

Views of PLWHA and HCP are presented alongside each other for themes 1 and 2, allowing a demonstration of themes within and across participant groups. For theme 3, data were presented from HCP only because theme 3 was captured in HCP topic guide only and not in PLWHA one. This was necessary as the researcher wanted to understand from the perspectives of HCP (since they deliver care to PLWHA) issues/ challenges in relation to person-centred care delivery in the context of HIV management. The themes and subthemes are described in turn below, and illustrative quotes with unique identifiers (participant group with their respective ages and genders) provided to support the themes.

5.2.4.1 Theme 1 Care structures are not currently built around the person

Participants discussed multifaceted factors including discrimination, stigma, and care structures and processes that hinder access to HIV care services.

5.2.4.1.1 Discrimination and stigma

HIV related stigma and discrimination remain a major barrier to PLWHA accessing care services. Discrimination and homophobic behaviours from HCP prevented PLWHA from accessing services at both private and public health facilities:

> “Due to mistreatment from health workers some of us stopped attending such clinics until we find a place where we are treated as human beings. Another issue is when you attend the clinic and you are a man with the complains of diarrhoea, even without asking you what or how did the diarrhoea started, staff just assumed that you are gay they will just leave you there without any medical assistance, is as if they wish you die at that moment with your symptoms. This is very demoralising you know most importantly when you soil yourself with the diarrhoea, no health worker is even willing

to change your soiled clothes or linen, this really gives you a low spirit and also you begin to have self-stigma." (QID9 PLWHA, male, age 25).

Participants also described perceptions and experiences of stigma related to an HIV diagnosis. Stigma emerged as self-stigma, as well as perpetrated by family and community. Expectations and experiences of stigma were a major barrier to accessing care services:

"Stigma is also another major barrier that prevent PLWHA from being free in themselves and to utilise the services available for them. Sometimes when you are being nice to the clients, they don't understand why you should be nice to them because they have always been stigmatised even at health facilities" (SQID4 HCP, female, age 46).

5.2.4.1.2 Fear of status disclosure

Fear of recognition as someone living with HIV also acted as a barrier to accessing care. For example, signposts placed in front of clinics describing services provided at the clinic (including HIV and related services) was identified as a barrier for PLWHA to accessing the clinic:

"I think a good care should be delivered in the community where it is near to the community members to access however, there should not be any signpost indicating that the clinic cares for HIV/AIDS clients, otherwise people will start to know our status and we may have to abandon those community clinics for other ones that are not closer to us" (QID13 PLWHA, male, age 26).

These barriers were also recognised by HCP who emphasised effects of these signposts in front of the clinic:

"We had enough signpost around the community however, some members of the community realising what we do, begun to label any client that comes to the clinic, some even went to the extent of discriminating against some of our staff because they cared for PLWHA" (SQID1 HCP, male, age 32).

5.2.4.1.3 Dual burden of disclosure of HIV status and sexual orientation

For MSM, the dual burden of disclosure of HIV and sexuality were a major concern since same sex relationships have not been legalised in Ghana. Participants felt they could not disclose their sexual orientation to family, friends or work colleagues for fear of homophobic reactions from these people. Unable to disclose to their families, some MSM described challenges when family members found out about their HIV or relationship status themselves, causing high levels of distress:

> "My family has not accepted me with my HIV status, my dad doesn't talk to me, he only talks to me when he thinks I should conform to his rules then he will address me with my status; my house is like mummy and daddy makes the rules and you are only to conform but I am very stubborn, so I don't usually obey what mum and dad says so it looks like I am the odd one out. My mum keeps reminding me of how she is at risk of getting HIV from me, dad also tries to say things that will make me feel guilty like he will say things like I am a disappointment to the family and telling me to give birth because he thinks am going to die soon" (QID4 PLWHA, male, age 20).

5.2.4.1.4 Poverty, community care and waiting times

Furthermore, many participants described poverty as their biggest barrier to accessing appropriate care. Although ART is dispensed free of charge, PLWHA have financial difficulties that prevented them from attending and accessing services or adhering to treatments, such as the cost of transport to and from the clinic:

> "The main discussion has been around finances because even though the ART is free, there are other supplementary drugs or lab investigations that clients need to do. Generally, clients think that because the HIV/AIDS treatment is free, everything else that comes with it should be free; others may also come, pay for all their treatment and when it is time to go home, they tell you they don't have money for transport. So the clinic has to find a way to pay for their transport or if these clients live close by, then the clinic vehicle will take them home" (SQID3 HCP, female, age 32).

For some, this was compounded by the decision to travel long distances in order to access care far from home to avoid being identified by people in their own community:

> "The main thing that will prevent me from attending my appointments will be when I don't have money to take car to the clinic because I don't have a straight car from my house to the clinic, I had to chatter a taxi that will bring me closer to the town before I take a commercial vehicle from town to the clinic. And I don't want people to see me going to the clinic and be asking questions" (QID8 PLWHA, female, age 43).

The importance of care services being located in the community and flexible to the needs of PLWHA was however recognised. Most participants described wanting their care to be available in community and with walk in services to enable easy access to care when needed and when it is possible for them to attend:

> "I think that the care in the community is good because it is less formal and you don't need an appointment to go to the clinic" (QID1 PLWHA, female, age 52).

However, extended periods of waiting in the clinic, where their status may be disclosed was an additional barrier to accessing care for PLWHA:

> "I expect that the moment I arrive in the clinic, they will just see me, give my medications then I go because we MSM we know ourselves and I am a bit popular too so when I am delayed in the clinic, other MSM will come to the clinic and identify me the same way I will identify them, and they will go and talk about the fact that they saw me in the clinic and the rest of us will like to know why I was at the clinic" (QID20 PLWHA, male, age 27).

5.2.4.1.5 Care communication and continuity of care

HCP described the importance of careful communication to retain PLWHA in care and ensure adherence to their ART. Due to the stigma associated with HIV and ART, HCP identified creative and innovative approaches of discussing and reminding PLWHA about medication including the use of figurative language and metaphor:

> "So now the concern is what can we do to keep our clients in care? And because clients take their pill every day when you go back to talk to them that please take your pills, they feel derailed, they want to see other innovations that are interesting to them like, pill boxes, colourful text messages. I noticed that most of my clients don't want to hear you asked them have you taken your drugs, so I have started using things like pebbles, so like have you taken your pebbles, just things that will not remind them of what they are taking. Most of them are getting used to it that I get messages from them like 'my pebbles have finished can I come and get some more?" (SQID10 HCP, male, age 33).

Communication between PLWHA and HCP was further described in relation to topics of discussion. PLWHA described interactions with HCP being mainly focused on their HIV and ART, not broader psychosocial domains:

> "Staff usually speak to me about my ART and how to take my medication regularly so that my viral load will go down. But they don't ask me about my home and my life outside HIV" (QID2 PLWHA, female, age 43).

They also described frustration due to lack of continuity of care, with staff changes undermining relationship building and discouraging disclosure of concerns:

> "It's also important to me that the same staff is maintained at the clinic because I hardly open up to people about my issues and concerns. The last time I came I met a doctor who was nice to me so I started sharing my issues and concerns with her but today when I came to the clinic, the doctor that saw me is a new doctor as a result, I couldn't discuss my issues and concerns with her because she is new to me and I have to try and develop a relationship with this doctor before I can open up to this doctor about my issues which will really take a while to happen" (QID9 PLWHA, male, age 25).

5.2.4.2 Theme 2 Priority outcomes and components of PCC

When asked what mattered most to them, PLWHA described outcomes across broad domains of need including symptoms, living a "normal life", marriage, having children and being employed.

This strongly contrasts those outcomes identified by HCP, which focused on biomedical outcomes such as achieving high CD4 counts and lower viral loads; and adherence to treatment with normal kidney and liver function tests.

5.2.4.2.1 Physical, psychological, social and spiritual wellbeing

PLWHA described the need for support for symptoms and concerns in four domains: physical, psychological, social and spiritual.

Participants described a range of physical symptoms that affect their activities of daily living, wellbeing and quality of life:

> "I have headaches, pain, fatigue and weakness in my body which sometimes prevent me from going to work. The pain can be unbearable to the extent that I am not able to get out of my room." (QID17 PLWHA, female, age 42).

Living with HIV also impacted significantly on the psychological wellbeing of PLWHA. In particular they described worries for their future, fears regarding disclosure of their HIV status, and, regrets and anger regarding contracting HIV, and how it has affected their life to date:

> "I worry most of the time about how I got HIV, I feel if it hadn't been for this HIV, I would have achieved greater heights in life. I feel that being HIV positive has really drawn me back in life, this makes me sad and am filled with regrets." (QID2 PLWHA, female, age 43).

This psychological morbidity was compounded by the social, economic and physical environment for PLWHA. They particularly expressed concerns about lack of family support, unemployment, and lack of money to support them self and their family:

> "My husband does not treat me well since he got to know my HIV status. He won't look after the children and he will insult me sometimes in front of the children making me feel that I am not a human being. I don't have any money because when I got HIV and news of it went round, it made people stopped buying from me which has rendered me

jobless because people feel they will get HIV if they buy from me or even talk with me." (QID10 PLWHA, female, age 35).

The overwhelming impact of HIV across physical, psychological and social domains resulted in PLWHA questioning the meaning of their existence. They described spiritual distress, feeling the need to be at peace with God, and the importance of spiritual support to engender hope and bring meaning to their lives:

"May be God is even the one who punished me with the HIV because when I had a girlfriend I was not diagnosed of HIV until I started dating a man. I don't really understand my life anymore, I am always praying for God's forgiveness." (QID13 PLWHA, male, age 26).

5.2.4.2.2 Family and intimate relationship

Concerns for PLWHA also extended to intimate relationships. They described a need for person-centred care that also addressed these relational needs, in particular information about starting sexual relationships with an HIV negative person and having children:

"What I want to ask staff, is about me and my wife, we want to have another child but we are not sure if we can have a child whiles on treatment or if it is even possible to have children at all because we have been advised to have protected sex so we are not sure if we can have unprotected sex let alone have a baby. I have been thinking about this for a while now but have not had the courage to ask the doctor or any other staff" (QID15 PLWHA, female, age 41).

PLWHA also expressed uncertainties around fertility and their ability to have children while living with HIV, particularly in the cases where one partner is HIV negative. They described a lack of information on these resulting in them questioning the future of their relationships:

"I just wanted to have unprotected sex with this other woman so that perhaps she might get pregnant for me, then I can have a child of my own because after my wife had the still birth I wasn't sure if she will be able to carry another pregnancy for me so that is

why I decided to date this other woman to see if I stand the chance of having another child even if it is outside my marriage who cares" (QID7 PLWHA, male, age 43).

5.2.4.2.3 Involvement in care and personalised care

In addition to the inadequate information, PLWHA also felt they were not actively involved in making decisions about their own care, as involvement in care was rare and they felt unable to have a say:

"I am not involved in my care and staff don't ask me my opinion about my care. I am not sure if I have a role to play in my care if I do, then staff have not told me about the role I need to play in my care. Staff don't ask me what matters to me and I don't think I have a say in my care." (QID5 PLWHA, female, age 36).

PLWHA described a need for care that addresses what is important to them, involving them meaningfully in care decisions, and delivered by professionals who are interested in them as a person and not only their HIV:

"Staff should have other conversations with us regarding other aspects of our life apart from HIV. Staff should also ask us about what is most important to us so that we can tell them about it. Staff should not assume they know all things, they should also treat us like human beings because our HIV status is not written in our faces to scare them of, we are human beings just like staff" (QID21 PLWHA, male, age 61).

5.2.4.2.4 What is person-centred care?

Some HCP did recognise the construct of PCC, describing the importance of considering the psychosocial and spiritual needs of the individual in order to see beyond the HIV diagnosis to the whole person:

"Like dealing with PLWHA is very different because when you are caring for PLWHA you are psychosocially and spiritually involved with their issues that are related or intertwine, so you see that you are sitting there trying to help someone's child enrol in school, or you are talking to somebody's husband who is discriminating against her. So

you are involved in so many levels, and that is what is interesting about HIV care, because strictly PLWHA mainly come here for their counselling and medication refill but what we need to have at the back of our mind is we are not focusing on just HIV, we are dealing with a whole human being" (SQID4 HCP, female, age 46).

However, HCPs described PCC differently, as 'tailored care' and 'targeted care':

"When we talk about person-centred care it should be having tailored care or targeted care because people are different. For me person-centred care is having differentiated models that will suit their needs. So we call it targeted care because a married man walking to the clinic who is HIV positive will have different needs to a young man who is HIV positive, and it will also be different with MSM who walk into the clinic." (SQID5 HCP, male, age 34).

Although this care is targeted toward the individual, decisions around what that care should include, and care needs are led by the HCP's view of what is important not by the expressed priorities of PLWHA.

5.2.4.3 Theme 3 Re-engineering HIV care to be more person-centred

5.2.4.3.1 Achieving person-centred care

HCP identified a need for training to understand what PCC means and how it could benefit PLWHA:

"Yes, it is possible to practice person-centred care but only when we are trained to understand what it means to be person-centred and what benefit it will be to PLWHA. Because what I observe is that one doctor mostly consults on Saturdays due to her busy schedules on weekdays; but because of her approach to caring, most of the PLWHA prefer to come for the Saturday clinic" (SQID1 HCP, male age 32).

Alongside training for professionals, HCPs identified the need for support in coordinating and integrating adjunct services to address the holistic care needs of PLWHA, and more evidence

from research undertaken in Ghana, that reflects the local needs and culture to inform service design and delivery:

> "I think the only thing we need to do is what we call integration of services and resource ourselves to do more capacity building and training for health workers to understand what person-centred care means so that they are fit to handle some of problems and concerns of PLWHA. Another thing too is that we need to do a lot of research because for us in Ghana we need research to tell us what influences what we do and because we don't have the research most of the time we do things the old way" (SQID10 HCP, age 33).

HCP also outlined challenges related to resources required to deliver PCC, including financial, human and time resources:

> "I think we need both financial and human resources because before you can have a discussion with a client with psychological issues to come out smiling you need more than 30minutes with that client. And as you are having such conversation with clients you will realised that there are financial issues that you may need to help the client with, like paying their transportation etc. I find it difficult to ask my client 'what is really bothering you?' And I am not happy that when clients share such problems, I am not able to help them so I will rather not ask" (SQID12 HCP, male, age 35).

They also identified challenges specifically in relation to providing care for key populations. One solution proposed was to train selected staff in providing care to these highly stigmatised communities, and to support their specific needs:

> "Or we can also identify and train staff to be able to handle such things, because we have at least 5 nurses we can identify at least 2 nurses who can be trained to support our clients especially MSM with these psychological issues, then we know we have such team in place. We should also focus our conversation on the client like trying to find out what is happening in the person's life before touching on HIV related issues at the tail end of the conversation" (SQID2 HCP, age 38).

5.2.4.4 What constitutes person-centred care for PLWHA and HCP

This data provides novel insight into what constitutes PCC for PLWHA beyond the original western-oriented concept. The four sub-themes 'physical, psychological, social and spiritual wellbeing', 'family and intimate relationships', 'involvement in care and personalised care' and 'what is person-centred care?', which emerged from the main theme "priority outcomes and components of person-centred care", relates to the component of PCC envisaged by both PLWHA and HCP in Ghana.

PLWHA described a need for care that is focused on addressing their physical, psychological, social and spiritual wellbeing, that involves them in care decisions and delivers personalised care to them. For HCPs, most expressed a need for human and financial resources and training in order to undertake holistic assessment and practice PCC.

While some views regarding PCC were common across the PLWHA and HCP interviews, others were specific to one or other of the participant groups. Both PLWHA and HCP in Ghana described PCC as care that should be delivered in the community, free from stigma and discrimination, that addresses financial, human and time resource issues. We present a conceptual model of PCC in Figure 17, demonstrating the differences and commonalities of views expressed by participants.

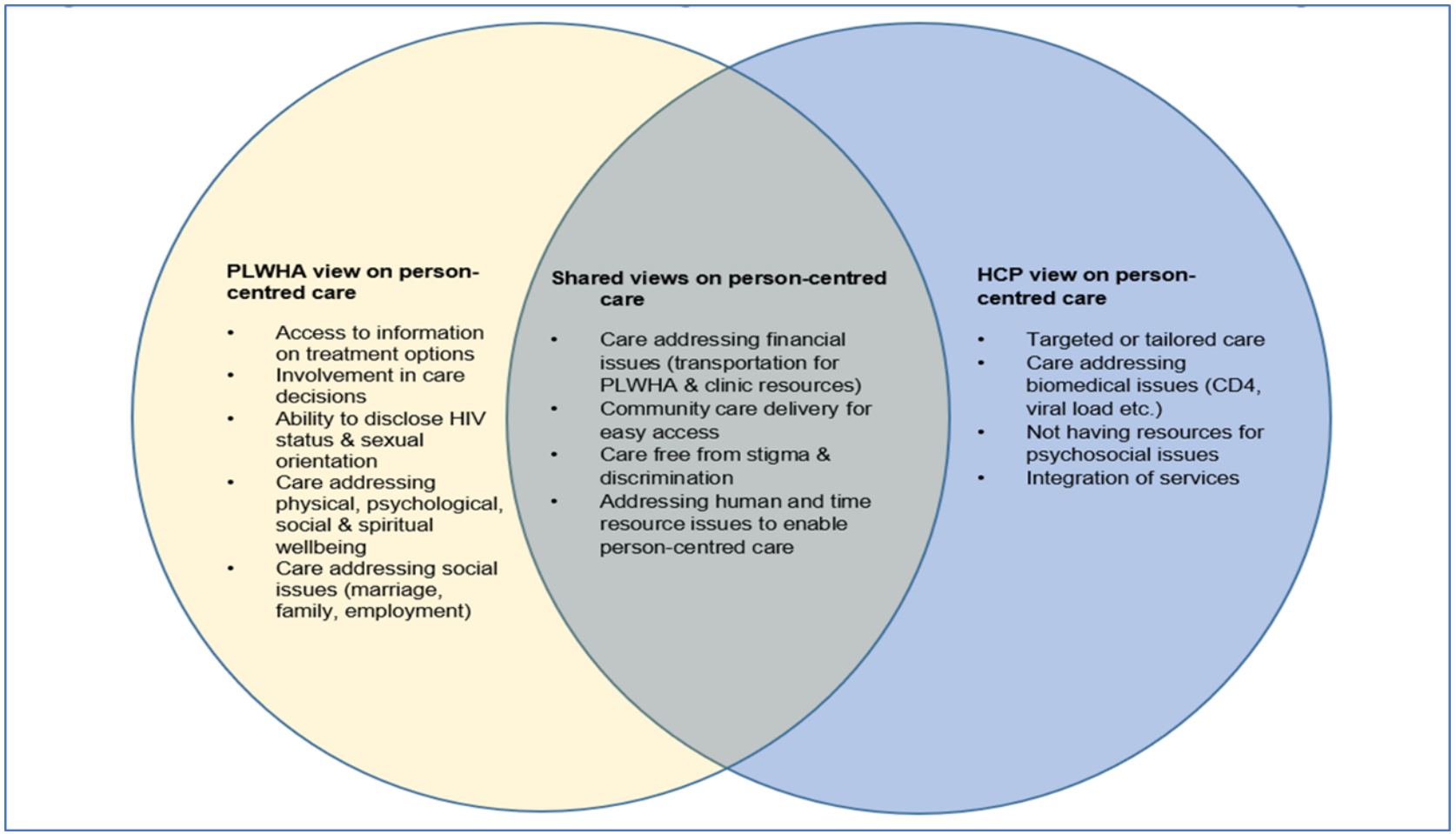


Figure 17: A conceptual model of person-centred care from the perspectives of PLWHA and HCP in Ghana

5.2.4.5 Views of PLWHA and HCP on person-centred care

PLWHA and HCP expressed common and differing views on what PCC care is and what outcomes matter to them. PLWHA understand PCC as care that involves them in their care decisions, which is concerned about the whole person and not only treatment adherence and viral suppression and addresses what matters to them. PLWHA also view PCC as addressing broader social issues: living a normal life ('like anyone else'), getting married and having children, and being employed. In contrast, HCP described PCC as 'tailored care' and 'targeted care', however, this was focused on their own perspectives as to how they would 'target' or 'tailor' care according to an individual's characteristics, rather than through the expressed needs of PLWHA. This was borne out in HCP data, which identified priority outcomes as biomedical (CD4, viral loads). This contrasts starkly with PLWHA data, which described social outcomes (living a normal life, getting married and having children). These differing priorities resulted in care that was not person-centred, as HCP expressed uncertainty about how PCC could be practiced, and a need for training [346]. Participants described perceptions and experiences of stigma related to an HIV diagnosis. Stigma emerged as self-stigma, as well as perpetrated by family and community. Expectations and experiences of stigma were a major barrier to accessing care services however, a recent study demonstrates the potential to increase PLWHAs' resistance to stigma using PCC delivery [382].

In order to implement and achieve PCC in community settings for PLWHA, there is the need for:

- Relationship building between stakeholders through effective communication, and acknowledgement of patients as experts in their own healthcare through partnerships that allow for sensitivity to patient's values, needs and preferences for care.
- Ongoing education and training for providers on PCC delivery, with a specific focus on holistic patient assessment, management of symptoms and concerns, collaborative care planning and delivery.
- Increased understanding of patient's perspective for PCC in order to inform the content of HCP training.

This data provides, for the first time, an understanding of the meaning of PCC in HIV population in Ghana, from the perspectives of key stakeholders. The next section mapped the contextual meaning and components of PCC as applied to PLWHA in Ghana onto a PCC theory to determine which components aligned with the theory and what extra components are required.

5.3 Thesis objective 3 findings

To map the qualitative data from objective 2 onto the components of person-centred care theory to determine which components mapped and what additional components are required.

Research question

What are the components of person-centred care (PCC) as applied to PLWHA in Ghana and how do these components map onto the theory of PCC?

5.3.1 Mapping the qualitative data onto the theory of PCC

The features of PCC identified from the qualitative data were mapped onto a theory of PCC (see Figure 18), to better understand the components of PCC as applied to PLWHA in Ghana. The mapping of the qualitative data was strengthened by the critical thought of how the context influenced the intervention, including the motivation and contribution of PLWHA and HCP and the divergent interpretations about how and why the process of change came about [383]. The key intervention features indicated that developing a PCC intervention required guidance and education/training in symptom control for HCP. Secondly, the person-centred intervention focused on addressing the holistic domains of need: physical, psychological, social and spiritual symptoms and concerns, alongside medical management of HIV.

The proposed process and outcome measures selected to measure the care process and outcomes were also mapped onto the PCC theory which ensured that these measures measure the intended outcomes expected. (see Figure 19).

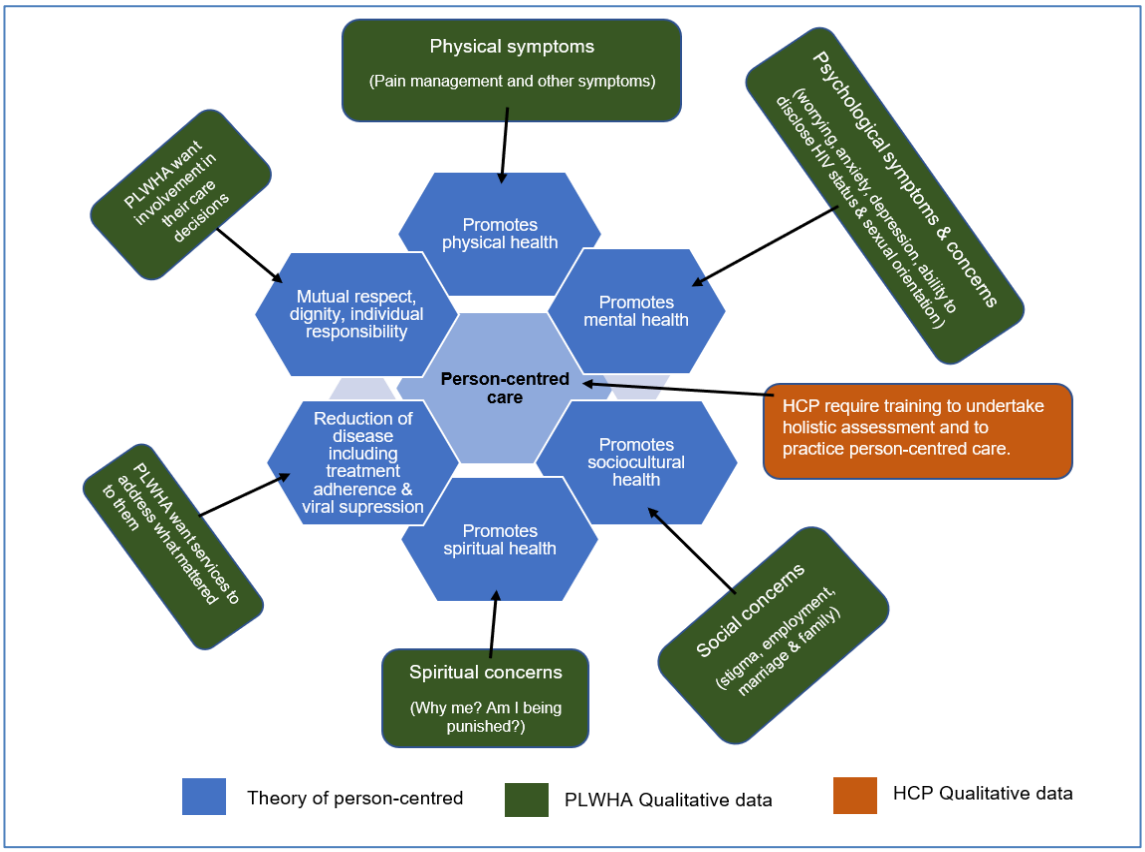


Figure 18: Qualitative data mapped onto components of PCC theory

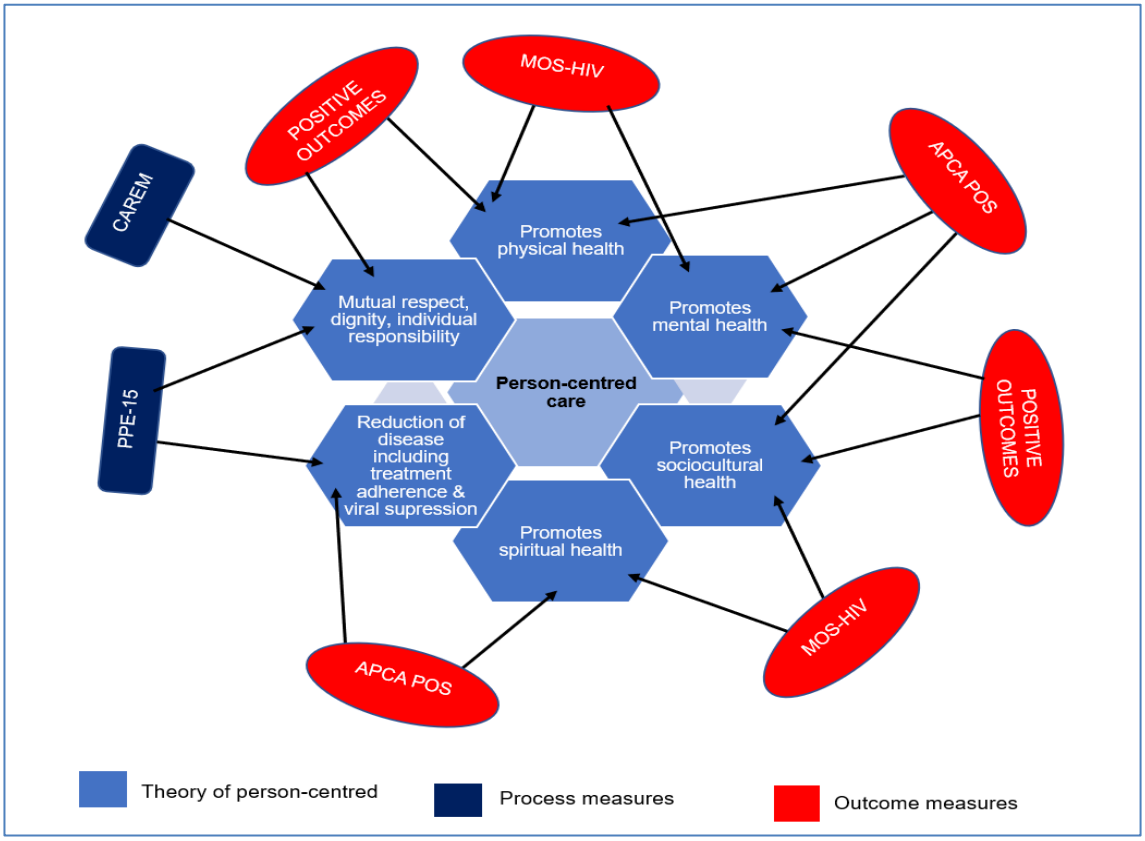


Figure 19: Process and outcome measures mapped onto components of PCC theory

5.3.2 Implication for intervention development

Key considerations for intervention development emerged from the qualitative dataset. PLWHA in a community setting in Ghana agreed that they want their care to address broader aspects of wellbeing beyond physical needs including psychosocial and spiritual wellbeing. The existing approach to delivering HIV care in the community focused primarily on the physical wellbeing of PLWHA and did not involve them in decisions about their care. However, HCP described concerns that PCC would only be possible if they were trained to deliver it. This implies that PLWHA require PCC interventions which are focused on addressing broader psychosocial and spiritual wellbeing and involves them in their care decisions to be added to existing HIV clinical management in order to meet their person-centred needs. The experiences shared by PLWHA provide important understanding of the context in which care is delivered, which can be used to tailor a PCC intervention. For example, the description of the psychological, social and spiritual symptoms and concerns, which are not currently being assessed and addressed in the current care, could be used to inform the intervention content. These domains of need could only be identified and addressed when HCP are skilled to undertake holistic assessment of the symptoms and concerns of PLWHA, as HCP in this study also emphasised the importance of training to acquire skills for holistic assessment and PCC practice.

Evidence suggest that study findings and recommendations for practice have not always been embedded successfully in the delivery of care resulting in variations in practice [34, 384-386]. It has been reported that 30 - 40% of care delivered to patients are not properly based on relevant guidelines, and, similarly disturbingly, 25% of patients receive improper or potentially harmful treatment [387]. The ToC for this study was vital to ensure study evidence could potentially be taken up, strengthening the paths to influence and impact.

Barriers to PCC in current HIV care delivered in community settings as highlighted in the qualitative data:

- Limited access to information on treatment options
- Non-involvement of PLWHA in care and care decisions
- Care not addressing physical, psychological, social and spiritual wellbeing,
- HCP fell unprepared to conduct holistic assessment and practice PCC

5.3.3 Framework to inform PCC delivery

Following this understanding of PCC from the perspectives of PLWHA and HCP, a framework to inform PCC delivery was developed informed by the WHO's framework on integrated people-centred health services [388], as shown in Figure 20. This framework detailed five key areas including clinic relationship building with PLWHA in identifying their general symptoms and concerns; skills training for HCP; building HCP-PLWHA relationship to create person-centred environments; PLWHA participation by involving and engaging them in their care decisions; leading to collaborative decision making between HCP and PLWHA, which could result in improving care outcomes and impact on the wellbeing of PLWHA.

The next section is the theoretical modelling of CECI components with selected outcome measures to establish the mechanism of impact.

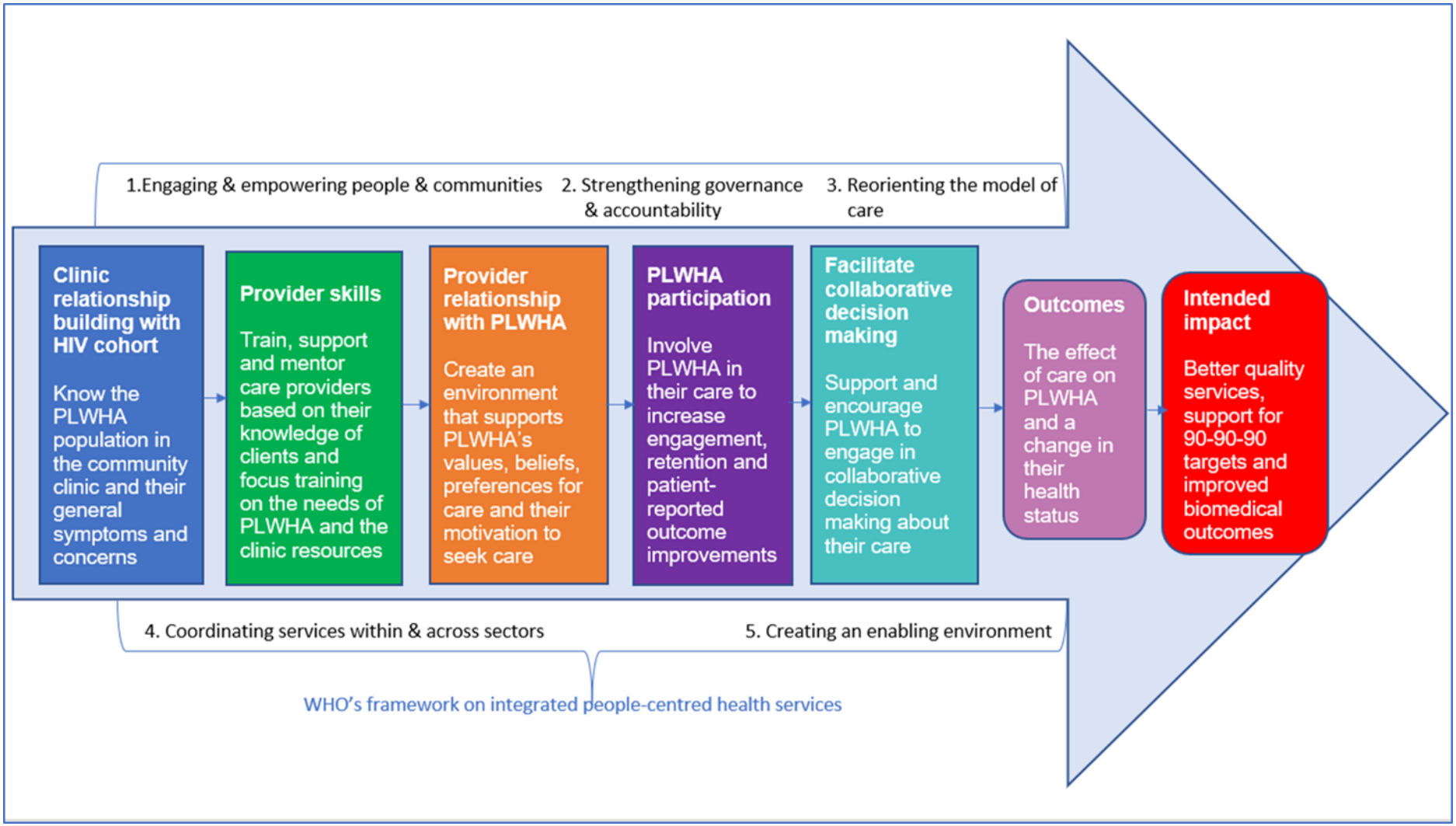


Figure 20: Framework to inform PCC delivery incorporated into the WHO's framework on integrated people-centred health services

5.4 Thesis objective 4 findings ("Modelling process and outcomes")

To integrate findings from objectives 1-3, modelling the potential processes, outcomes, and mechanisms of action for the intervention.

5.4.1 Main findings from thesis objectives 1, 2 and 3

Objective 1: PCC models of care delivered alongside HIV clinical management:

- Although models of person-centred HIV management are effective in improving physical, psychological, social and spiritual wellbeing, the evidence is weak.
- Exploration of contextual meaning and practice of PCC, development of more PCC interventions focusing on the specific contextual needs within the domains of physical, psychological, social and spiritual wellbeing of PLWHA; measuring these outcomes with validated tools; and additional examination of the feasibility and acceptability of such interventions were identified as potential future research direction.

Objective 2: A summary of views on current practice by PLWHA and HCP data include:

- Care is mainly focused on physical wellbeing,
- PLWHA not involved in their care,
- PLWHA not asked what matters to them
- HCP feel unprepared to assess psychological, social & spiritual problems
- HCP require training in order to assess and manage these domains of problems

Objective 3: Mapping of the qualitative data from thesis objective 2 onto the components of the theory of change (PCC):

- The qualitative that aligned with the components of PCC theory
- The only overlap was physical wellbeing, as PLWHA described their care was primarily focused on physical wellbeing
- The findings from these interviews and literature [48] strongly suggested that a person-centred and holistic approach was most likely to address the diverse symptoms and concerns experienced by PLWHA.

5.4.2 Results from expert intervention development workshop

Present at the half-day intervention development workshop were the researcher (MA-O) and experts including: RH – a health services researcher with range of experiences in outcome measurement and tool validation, HIV/AIDS care in sub-Saharan Africa and intervention development and testing; JD – an educationalist and palliative care clinician with a PhD that evaluated palliative care training in rural Uganda; KB – working on priority outcomes for people with HIV/AIDS and communication between health professionals and patients in clinical encounters, and how that interaction shapes the experience for patients and their families; KN - pain and symptom self-management among HIV/AIDS, designing, testing and evaluating nursing interventions; and EN - use of patient reported outcomes measures in African clinical settings, knowledge translation, information use and policy development.

These experts were assembled based on their wealth of experience in working with PLWHA and developing interventions in this population across Africa. The experts together with the researcher discussed the findings from the systematic review (thesis objective 1) and the qualitative interview findings (thesis objective 2) including the theory of PCC and identified the person-centred domains from the perspectives of PLWHA and HCP in Ghana. These findings were then mapped onto the PCC theory and determined the findings align with the theory and informed the components of the proposed intervention. The expert panel determined the need for the intervention, examined current practice, used HCP interview data to identify the training needs. The panel then recommended that the researcher draw on palliative care skills and existing manuals, documents and procedures used in the studies identified in the systematic review to develop the PCC training content for HCPs. The panel finalised the content of the training with a schedule for delivery, and person-centred domains with some specific symptoms and concerns described by participants with corresponding selected outcome measures to measure these domains in the feasibility cRCT.

This novel person-centred intervention developed addressed:

- The training needs of HCP on the use of a person-centred approach, holistic assessment of symptoms and concerns, collaborative care planning and delivery
- PLWHA involvement in care and care decisions
- Information needs and collaborating with HCP in planning care and delivery.

A logic model (Figure 21) of the proposed intervention was developed demonstrating detailed components relating to context, training, implementation, mechanism of action and outcomes of the CECI intervention. This person-centred approach is reflected in the broad content of the intervention and its steps of delivery, including the training of HCP. PLWHA support the intervention components targeting broader domain of needs including physical, psychological, social and spiritual wellbeing in addition to involvement in their care decisions.

5.4.2.1 Purpose of the intervention

The overarching purpose of this person-centred intervention is to optimise HCP's skills in the holistic assessment and management of symptoms and concerns of PLWHA using a person-centred approach. This was achieved through the development of a training content and a schedule that was used to train HCP on how to deliver care using a person-centred approach. The person-centred approach brought together PLWHA's priorities for care through person-centred holistic assessment using a holistic assessment tool. The findings from the holistic assessment led to collaborative care planning between HCP and PLWHA in achieving care goals that mattered to PLWHA most.

The name 'community-based enhanced care intervention' (CECI) was chosen for the intervention to emphasise its community focus of delivery and an enhancement of standard HIV care.

5.4.2.2 Intervention description

CECI consisted of three-session training programme for HCP, holistic assessment tool which assessed physical, psychological, social and spiritual symptoms and concerns, a care plan which facilitated collaborative care planning and delivery, and a twice weekly mentorship and fidelity monitoring. Participants in the CECI arm received care delivered by their HCP who received the three-sessions training programme. CECI participants received a minimum of three appointments with HCP after the four-month course of CECI delivery. For each appointment, participants had their symptoms and concerns assessed in four domains: physical, psychological, social and spiritual wellbeing using a holistic assessment tool, then a care plan was used to facilitate collaborative care planning between HCP and PLWHA before care was delivered based on the care plan. The implementation of the CECI included four levels of activities: (a) HCP training on CECI delivery; (b) use of holistic assessment tool to assess symptoms and concerns, (c) a care

plan to facilitate collaborative care planning and delivery; and (d) mentorship and support for HCP with fidelity monitoring.

5.4.2.3 Mechanism of action/ impact of the intervention

Mechanisms of impact are the means by which CECI causes change resulting in an outcome. The theory of change (PCC) was used to support understanding of what mechanisms can be expected to result in desired outcomes and therefore influenced the selection of CECI components and its delivery. The theoretical mechanisms targeted by CECI involved physical, psychological, social and spiritual responses and approaches described in the logic model in Figure 21.

Figure 22 demonstrates graphically the sequential steps taken to implement CECI.

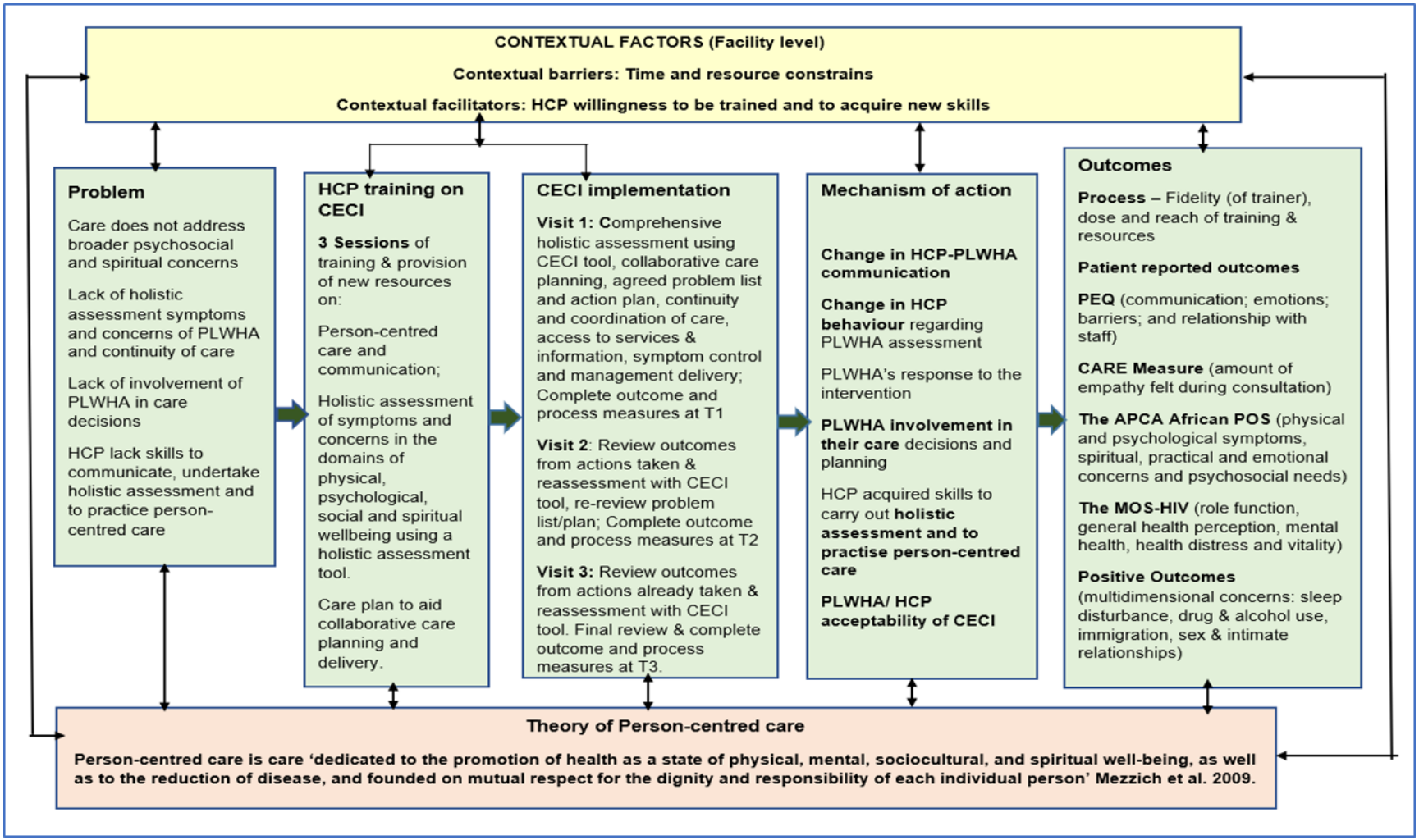


Figure 21: Logic model of CECI with detailed components relating to context, training, implementation, mechanism of action and outcomes

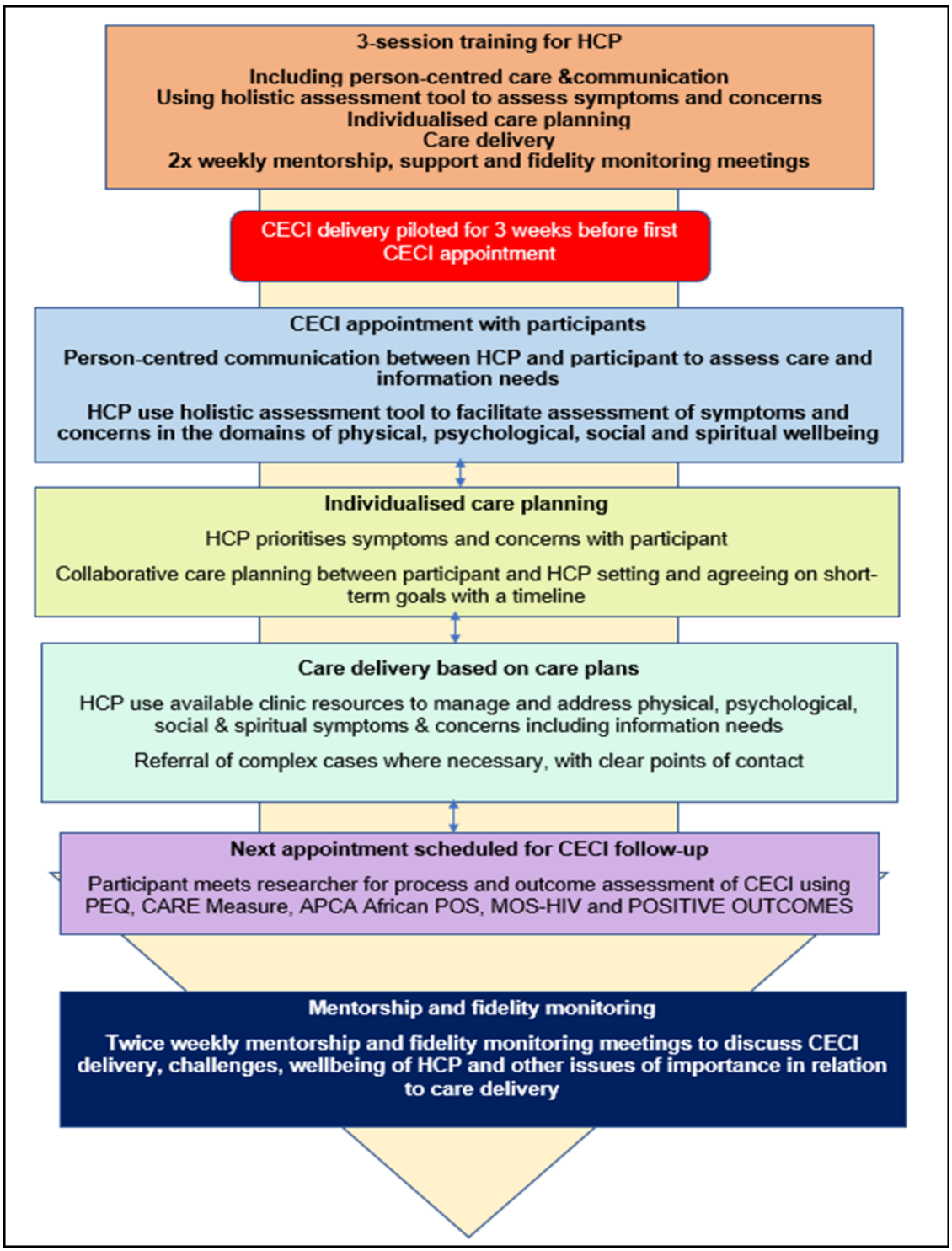


Figure 22: A graphical depiction of CECI with its sequential steps of implementation

5.4.2.4 Intervention training content and schedule

The intervention training contents consisted of five modules on communication and person-centred care; physical wellbeing; psychological wellbeing; social wellbeing and spiritual wellbeing (see Table 20 for training content and schedule).

The outcomes of care delivered were measured using selected outcome measures which have been mapped onto the specific symptom and concerns domains described by participants (see Table 21).

Table 20: Intervention training content and schedule for HCP

Days	Time	Training modules	Data source
Monday	3pm to 4pm	**Module 1: Communication and Person-centred care** Communication skills guidance Holistic care (assessment of physical, psychological, social and spiritual problems and concerns) Refreshments	Qualitative data
Tuesday	3pm to 4pm	**Module 2: Physical wellbeing** Assessment and treatment of pain Assessment and treatment other symptoms Assessment and treatment medication side effects Refreshments	Qualitative data/ systematic review
Wednesday	3pm to 4pm	**Module: 3 Psychological wellbeing** General counselling and emotional support Treatment of psychological problems such as depression and anxiety Support with disclosure and use of support groups Refreshments	Qualitative data/ systematic review
Thursday	3pm to 4pm	**Module 4: Social wellbeing** Help with managing stigma and discrimination Social isolation Assistance with financial and other material needs Refreshments	Qualitative data/ systematic review
Friday	3pm to 4pm	**Module 5: Spiritual wellbeing** Spiritual counselling Life review counselling Respecting beliefs and practices Course Summary/ Overview Presentation of certificates on course completion	Qualitative data/ systematic review

Table 21: Person-centred domains described by participants mapped onto selected outcome measures

Person-centred domains	Symptoms/ concerns	Source of data	Selected outcome measures
Physical	Pain Fatigue Weakness	Qualitative development interview data	**APCA POS** (physical and psychological symptoms, spiritual, practical and emotional concerns and psychosocial needs) **MOS-HIV** (role function, pain, physical functioning, cognitive functioning, social functioning, general health perception, mental health, health distress and vitality) **Positive Outcomes** (physical and emotional health and wellbeing, home and social life, sex and intimate relationships)
Psychological	Anxiety about the future Depression Fear of pain/death Insomnia	Qualitative development interview data	APCA POS MOS-HIV Positive Outcomes
Social	Social isolation Worry about family Loss of income Loss of family role Stigma	Qualitative development interview data	APCA POS MOS-HIV Positive Outcomes
Spiritual	Why me? Am I being punished by God? What is the value of my life? What will happen if I die	Qualitative development interview data	APCA POS MOS-HIV Positive Outcomes

Participants also described concerns regarding the process of care delivery, and some of these concerns are listed in Table 22, with selected process measures to measure the domains described by participants.

Table 22: Process of care delivery described by participants mapped onto selected process measures

Care process domains	Specific concerns	Source of data	Selected process measures
Involvement in care	Lack of information on treatment options	Qualitative development interview data	**PPE-15** (measures patient experience along the domains of communication; emotions; short-term outcomes; barriers; and relations with staff) **CARE Measure** (measures the amount of empathy that a patient feels they have received during a consultation)
	Not asked what mattered to them		
Collaborative care planning and delivery	Not have a say in care decisions	Qualitative development interview data	PPE-15 CARE Measure

5.4.2.5 CECI structure and flexibility of delivery

CECI allowed for a high level of flexibility in its delivery. CECI is intended for PLWHA especially those receiving care in community settings and the only indication for use was to be diagnosed with HIV for at least six months. HCP trained to deliver CECI at the intervention site were given copies of CECI content and sequential steps of delivery, which ensured HCP's confidence to deliver CECI according to the processes set out in the steps.

At the first CECI appointment, HCP informed the patient about the aim and scope of CECI and invited questions. This was followed by a person-centred assessment using the holistic assessment tool, which guided the care interaction, engaged and elicited participants' concerns. The HCP and participant agreed on priorities and concerns that could be addressed during care planning and delivery. Strategies were selected and personalised to address the priorities and concerns set out in their care and action plan. The second and third CECI appointments followed the same structure. The initial part of the appointment included a review of the participant's current wellbeing, priorities, concerns and action plan from the first appointment. Towards the end of the second appointment, HCP began to warn participants that the next appointment will be the last CECI appointment.

Structured documentation for recording CECI delivery supported recording of CECI components delivered including process items (time of first appointment and mode of delivery, duration, involvement and number of sessions) and outcome items (physical, psychological, social and spiritual wellbeing). HCP were supported to reflect on CECI delivery, highlighting non-specific treatment effects identified and any enablers or challenges to CECI delivery.

5.4.2.6 Holistic assessment and care planning

The HCPs delivering CECI used a holistic person-centred approach during participant assessment to elicit and identify symptoms and concerns. They assessed wellbeing in the domains of physical, psychological, social and spiritual aspects of life. The HCP supported the participant to express their expectations of care. During the opening conversation, the HCP assessed for cues which indicated any immediate and pressing concerns that the participant had, these were verbally or non-verbally communicated. If present, the HCP began the assessment by exploring these concerns first. If no immediate concerns are reported, the HCP continued and supported participants by encouraging them to participate and contribute to their care decisions. HCP also explored the daily life roles and activities that are important to participants to identify any pressing issues. If symptoms and concerns are not volunteered, the holistic assessment tool with specific questions in the domains of physical, psychological, socioeconomical and spiritual screening questions were used to holistically assess participants wellbeing. It was assumed that the presence of symptom and concern was distressing or that the participant was unable to resolve these symptoms themselves. Therefore, HCP asked participants about their own thoughts about how symptoms were impacting on their wellbeing, how they perceived the causes, consequences and potential solutions.

5.4.2.7 CECI care process implemented with PCC as the ToC

PCC was the ToC which underpinned the implementation of CECI, see Figure 23 for how the ToC influenced the CECI intervention.

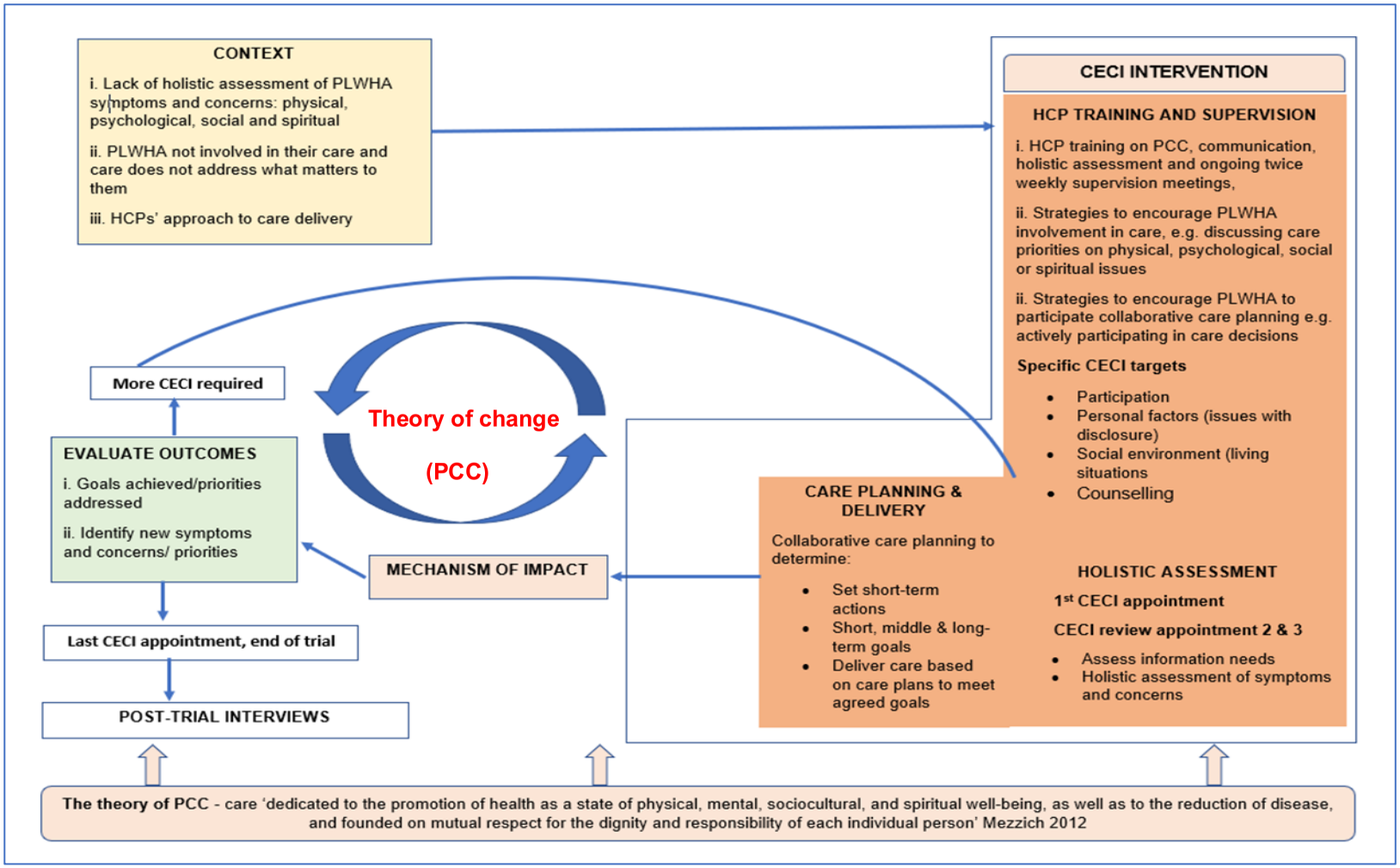


Figure 23: CECI care process with PCC as the ToC

Chapter 6 Results 3. Phase 3 (thesis objective 5)

To deliver and test the feasibility of a cluster randomised controlled trial of the intervention in terms of recruitment and retention, and to determine intervention delivery, estimate of potential effect and suitability of measures.

6.1 Mixed methods feasibility testing of CECI

Feasibility testing of CECI was conducted as recommended by the MRC guidance [176] to determine its feasibility and acceptability. Testing was conducted through a parallel mixed methods design with post-trial qualitative exit interviews. This section reports on the results of the feasibility and acceptability of CECI including the feasibility of recruitment and retention of PLWHA, acceptability of CECI by HCP and PLWHA, and estimate of potential effect size of CECI. Results on the primary outcomes was presented followed by the that of the secondary outcomes. Figure 24 represents how the feasibility cluster RCT is situated in the overall study plan implemented using the MRC guidance.

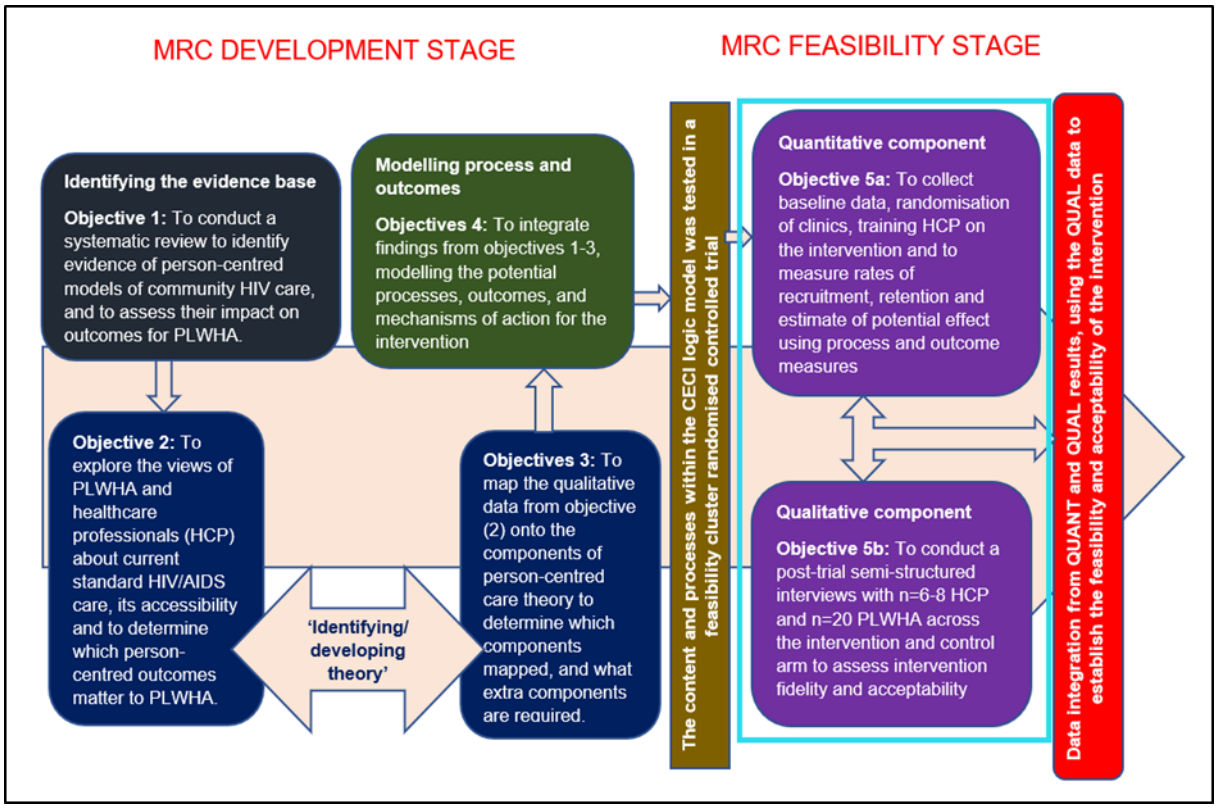


Figure 24: Feasibility cluster RCT of CECI as situated in the overall study plan

6.1.1 Primary and secondary outcomes

The primary outcomes for this feasibility cluster RCT were:

i. Recruitment rate

ii. Retention rate

Secondary outcomes

i. Fidelity of the intervention training and delivery

ii. Intervention delivery and acceptability,

iii. Estimate of potential effect size

6.1.2 Participating clinics

Recruitment and baseline data collection started from July 2018 at two HIV community clinics: West African AIDS Foundation (WAAF) and the HIV clinic at the Public Health Unit of Legon Hospital. These clinics are situated about 6.2km apart in the Greater Accra Region of Ghana. WAAF currently provide HIV care services to a cohort of 750 PLWHA with an average of 15 to 40 PLWHA seen daily, whiles the Legon HIV clinic also provide HIV care to a cohort of 500 PLWHA with an average of 10 to 30 PLWHA seen daily.

6.1.3 Screening and recruitment

For the primary outcome, n=83 PLWHA were screened of which n=69 (83%) were eligible. Nine of those eligible declined participation and n=60 (87%) consented and were recruited into the trial within 6 weeks of recruitment starting. Recruitment was rapidly rolled out in these clinics with the aim of achieving an average recruitment rate of 5 participants per week at each clinic. Recruitment at the Legon clinic closed a week ahead of WAAF. An overall recruitment rate of 16.7% per week was achieved with 5 accruals per week at each site. See Table 23 and Figure 25 for participant screening and recruitment details. Following randomisation by ratio of 1:1 to intervention and control, 93%, 98% and 97% completed follow-up outcome measures at month 1, month 2 and month 3 respectively. The CONSORT extension for feasibility trials was used to report participants flow through the trial.

Table 23: Records of participant screening and recruitment

Weeks of recruitment	**Total potential participants screened**		**Total potential participants eligible**		**Total recruited**	
	Clinic 1 (Legon)	Clinic 2 (WAAF)	Clinic 1 (Legon)	Clinic 2 (WAAF)	Clinic 1 (Legon)	Clinic 2 (WAAF)
Week 1	8	-	7	-	5	-
Week 2	8	7	8	5	7	4
Week 3	8	13	6	12	6	10
Week 4	9	8	7	6	6	5
Week 5	8	7	7	5	6	5
Week 6	-	7	-	6	-	6
Total	**N=41**	**N=42**	**N=35**	**N=34**	**N=30**	**N=30**

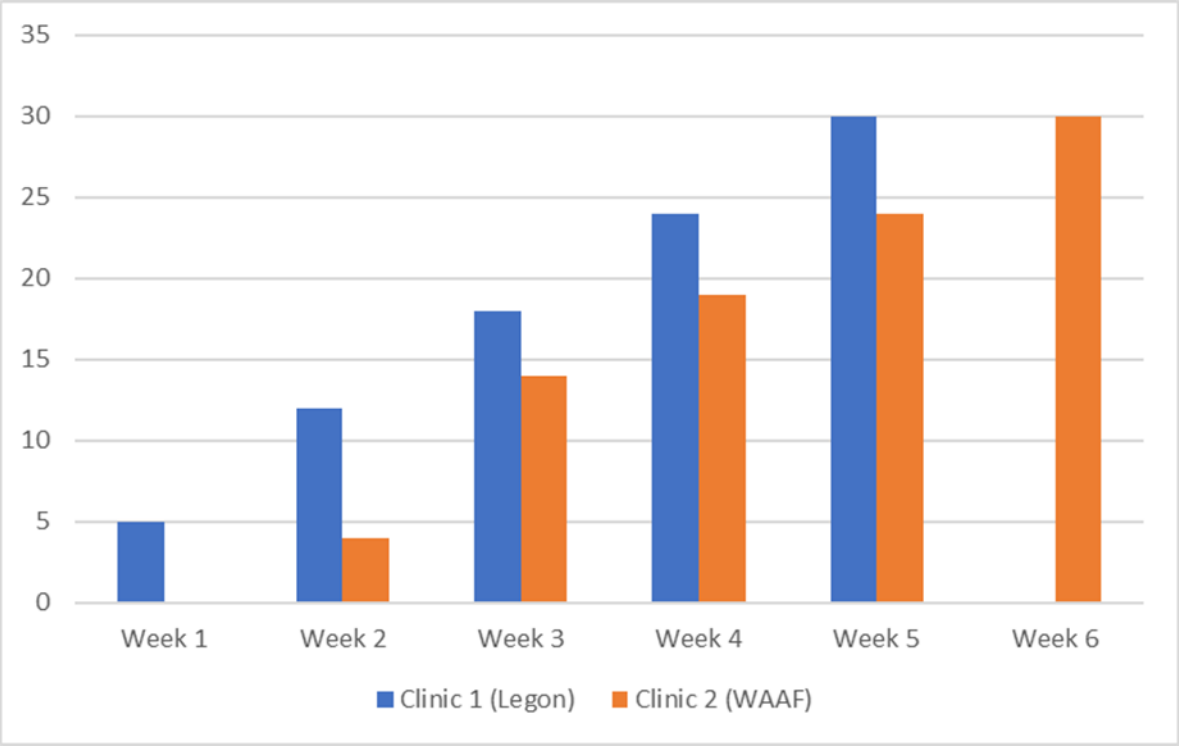


Figure 25: Accrual by clinic per week

6.1.3.1 HCP involvement in recruitment and achievement of recruitment targets

HCP in the respective clinics supported with participant recruitment by helping to identify potential participants and referring them to the researcher for further assessment. The participant screening logs were completed with the details of each participant screened, as HCP who helped in completing the logs reported that its completion was practical and feasible. The researcher was present at the clinics throughout the

recruitment period, which also motivated HCP interest to be involved in the recruitment process. During the recruitment and baseline data collection some participants expressed concerns about their inability to complete the outcome measures without the researcher's support in helping them to understand each question/ item on the measures. The researcher took these concerns into consideration and supported most participants with the completion of the measures by reading out and explaining the questions to participants before they provided their response.

The recruitment targets for both sites were achieved within 6 weeks (30 participants each) and the reason for PLWHA non-participation are described in addition to the researchers' experience of HCP involvement during the recruitment process. Going forward, the findings from this recruitment process will be useful in informing the inclusion criteria for a future definitive trial.

6.1.3.2 Reasons for non-participation in the feasibility trial

A screening log was kept across the two study sites to determine reasons for not approaching eligible PLWHA and reasons for refusal to participate in the study for PLWHA who were approached. See the CONSORT flow diagram [354] in Figure 26 for details of participant flow through the trial and non-participation. Nine PLWHA who met the inclusion criteria declined participation as four said they did not have time and the remaining five were not interested in participating.

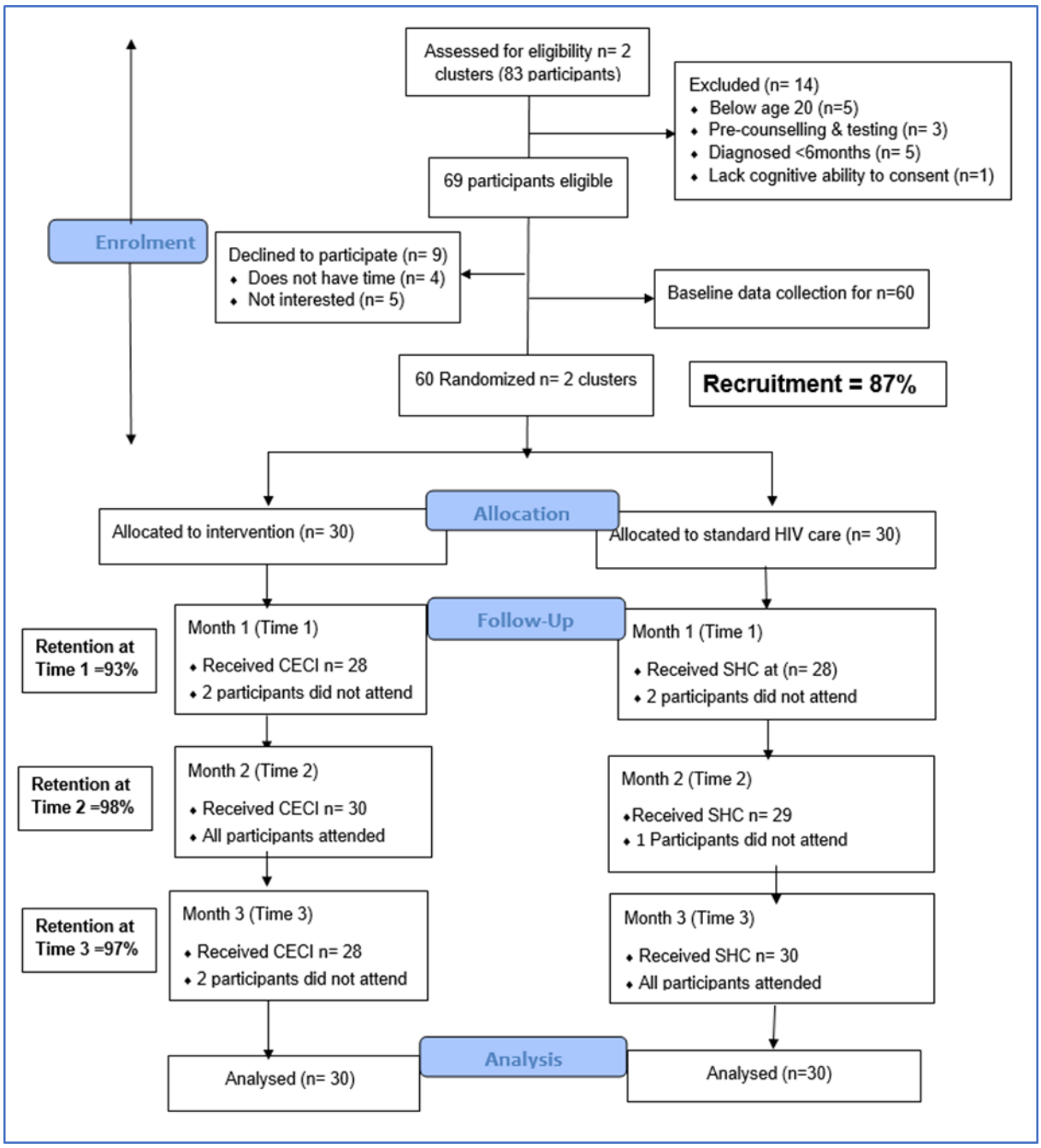


Figure 26: CONSORT extension for feasibility trials - flow diagram

6.1.4 Baseline and clinical data collection

Baseline characteristics of the consenting participants were similar in the intervention and control arms as presented in Table 24. There was no significant difference between the intervention and control arms with regard to age, gender sexual orientation, or CD4 count. The mean age of participants in the intervention was slightly younger compared with the control arm (36.6 vs 38.9) and the intervention had more female (18 vs 13) and heterosexual participants (25 vs 19). No statistical significance tests or confidence intervals were calculated for the difference between the randomised clusters on any baseline variables as this was a feasibility trial and the main outcome

of interest is recruitment and retention of participants. In terms of education, 43% of participants in the control arm had education up to the diploma level compared to 13.3% in the intervention arm. Also, whereas 50% in the intervention arm were educated to the secondary school level, those in the control arm was 23.3%. Additionally, in terms of employment, about 50% of participants in the control arm worked as the section of the middle class with the lowest social status, generally composed of shopkeepers, lower clerical staff, etc compared to 67% in the intervention arm; and 30% in the control arm were unemployed compared to 23% in the intervention arm. Most participants have partners 63% and 67% in the control and intervention arms respectively, with children and financial dependants. Also, with regards to the WHO clinical staging of HIV infection, 70% and 80% of participants in the control and intervention arms were in stage two respectively.

Table 24: Baseline and clinical characteristics

Characteristics	**Control arm (n=30)**		**Intervention arm (n=30)**		**Total (n=60)**	
	N (%)	**Mean (SD)**	**N (%)**	**Mean (SD)**	**N (%)**	**Mean (SD)**
Age (years)		38.9 (11.66)		36.6 (10.23)		37.75 (10.94)
Gender: female	13 (43.3)		18 (60.0)		31 (51.7)	
Sexual orientation Heterosexual MSM WSW Bisexual Missing	 19 (63.3) 5 (16.7) 1 (3.3) 3 (10.0) 2 (6.7)		 25 (83.3) 3 (10.0) - 2 (6.7)		 44 (73.3) 8 (13.3) 1 (1.7) 5 (8.3) 2 (3.3)	
Has a partner (yes)	19 (63.3)		20 (66.7)		39 (65.0)	
Number of children		1.37 (1.47)		2.07 (1.44)		1.72 (1.49)
Number of financial dependants		1.24 (1.27)		2.83 (2.48)		2.05 (2.12)
Education No school Primary Secondary Diploma ≥Degree	 1 (3.3) 2 (6.7) 7 (23.3) 13 (43.3) 7 (23.3)		 2 (6.7) 4 (13.3) 15 (50.0) 4 (13.3) 5 (16.7)		 3 (5.0) 6 (10.0) 22 (36.7) 17 (28.3) 12 (20.0)	

Employment status White Collar Worker Shop keepers Skilled Worker Unemployed Missing	 4 (13.3) 15 (50.0) 1 (3.3) 9 (30.0) 1 (3.3)		 3 (10.0) 20 (66.7) - 7 (23.3) -		 7 (11.7) 35 (58.3) 1 (1.7) 16 (26.7) 1 91.7)	
CD4 count (cells/mm^3)		363.59 (137.31)		366.91 (145.49)		365.12 (139.68)
WHO clinical stage Stage 1 Stage 2 Stage 3 Stage 4 Missing	 4 (13.3) 21 (70.0) 4 (13.3) 1 (3.3)		 - 24 (80.0) 4 (13.3) - 2 (6.7)		 4 (6.7) 45 (75.0) 8 (13.3) 1 (1.7) 2 (3.3)	

6.1.5 Secondary outcomes

This section reports on the secondary outcomes including fidelity of the intervention training and delivery; intervention delivery and acceptability; and estimate of potential effect size of the intervention and study design.

6.1.6 CECI training for HCP at the intervention site

A total of 3 training sessions was delivered to HCP in the CECI arm instead of the original 5 sessions planned. Originally, 5 sessions of one hour each was planned for the training of HCP and this was scheduled to cover the content of the training which included: person-centred care, communication and the holistic approach on day 1; symptom and concerns assessment, care planning and delivery for physical, psychological, social and spiritual wellbeing for day 2, 3, 4 and 5 respectively. However, this original schedule for the training was changed to 2 hours per session for 3 days in order to cater for HCP shift patterns.

The researcher expected mainly HCP in the category of doctors, nurses, counsellors and social workers to be at the training because these categories of HCP provide hands on care to PLWHA who mainly see these categories of HCP each time they visited the clinic. For these categories of HCP, the researcher expected n=10 to be at the training. On the first day of training n=13 HCP attended; then n=11 on day 2 and n=12 on the final day 3 (see Table 25 for HCP details). HCP reported in the training evaluation that there was improvement in their knowledge regarding physical assessment and that they acquired new skills with regards to holistic assessment.

Table 25: Details of HCP who attended the CECI training

Training days	Training duration	Category of HCP expected	Category of HCP present	N (%)	Total number of HCP present
Day 1	2-4pm	Doctors Nurses Counsellors Social workers	Doctors Nurses Counsellors Social workers Healthcare assistants Laboratory technician Human resource manager	n=1 n=5 n=2 n=1 n=2 n=1 n=1	N=13
Day 2	2-4pm	Doctors Nurses Counsellors Social workers	Doctors Nurses Counsellors Social workers Healthcare assistants Human resource manager	n=1 n=4 n=2 n=1 n=2 n=1	N=11
Day 3	2-4pm	Doctors Nurses Counsellors Social workers	Doctors Nurses Counsellors Social workers Healthcare assistants Laboratory technician Human resource manager	n=1 n=4 n=2 n=1 n=2 n=1 n=1	N=12

6.1.6.1 CECI implementation, adherence/ compliance

All the HCP who participated in the CECI training were actively involved in the delivery of CECI. CECI adherence was achieved; all 30 participants recruited and randomised to the intervention arm received CECI with each participant receiving at least two sessions, and no participant dropped out during CECI delivery. A total of 3 CECI sessions were completed one session each per month. Overall, 30 appointments were offered each month for 3 months, which n=28 (93%) attended at month 1 (T1), n=30 (100%) at month 2 (T2) and n=28 (93%) at month 3 (T3) respectively (see Table 26 for details).

Over all 100% of participants attended at least one CECI appointment and 7% did not attend at least one of their appointments. At the first and third (final) CECI appointment 97% attended, and then 100% of participants attended at the second appointment. The appointments were scheduled on a monthly basis and participants who did not attend their scheduled appointments had a two-week window to attend after a reminder call was placed to them. However, where a

participant failed to attend, it was counted as missing. Therefore n=2 participants each in the first and final CECI appointments failed to attend their appointments. At 3-month trial end point, only two participants were missing.

Each intervention session lasted 30 to 61 minutes and the length of each CECI session was adaptable to meet the needs of each participant.

Table 26: Details of intervention appointments attended

CECI delivery	Number of appointments offered	Number attended (n)	Time taken to complete each appointment	Attendance rate (%)	Absence rate (%)
T1	30	28	30-61 minutes	93	7
T2	30	30	30-61 minutes	100	0
T3	30	28	30-61 minutes	93	7

6.1.6.2 Outcome of the HCP mentorship and supervision meetings

The mentorship and supervision meetings were held twice weekly after HCP professionals were trained, and this continued throughout the trial. At these meetings, the intervention and how it was being delivered was discussed including the coping mechanisms of HCP in terms of the new interventions. Generally, HCP discussed their (i) adaptation to the intervention and delivery, (ii) how they felt about the intervention and their source of motivation to deliver it, (iii) how the intervention is changing their practice and (iv) challenges with time taken to assess and manage one participant, especially when the clinic was busy and other clients were waiting to be seen. The outcomes of these meetings are discussed in turn:

(i) HCP adjustment to CECI delivery: HCP discussed that the intervention delivery was a bit challenging at the start as it was their first time of using the holistic approach, so it took some time for them to get adjusted to the whole process of holistic patient assessment, collaborative care planning and delivery of care based on the agreed plan. HCP also noted that PLWHA were initially hesitant to contribute to their care decisions as this was a new experience for them as well. The researcher discussed with the HCP to use their initial rapport building with the participants to also warn them that they were expected to play an active role in their care and constantly encourage them to contribute to the process of care delivery. This information was reinforced throughout the trial period at each meeting as HCP fed back on these issues. HCP and the researcher also discussed their understanding of the person-centred holistic care process, which HCP said the

understanding of the process started on a lower level but they praised the weekly meetings as the major factor that increased their understanding of the person-centred care delivery process. They also discussed that, if the researcher had left them alone after the training to deliver the care without the supervision meetings, they would have given up on the comprehensive process of assessment, care planning and delivery.

(ii) Motivation to deliver the intervention: HCP discussed that most of them initially were just delivering the intervention out of curiosity to know the difference it will make compared to how they used to deliver care because they did not think that the input of PLWHA in their care would have made any difference. However, they were motivated to continue delivering the intervention as a result of the response they received from PLWHA, their enthusiasm and the joy on their faces when they were offered the opportunity to participate in their care. The researcher reiterated and discussed with HCP about the importance of making participants feel respected and valued members of the care team to build trusting relationships with them. HCP confessed that as the participants started trusting them, they became very comfortable with them and discussed issues openly.

(iii) Change in practice with the intervention: The tangible change in participants attitude towards the intervention corresponded to HCP changing their approach to care delivery as most of them discussed that they continue to engage the participants in the decision-making process towards their care. The importance of changing the approach to care delivery was discussed in association with the multidimensional problems that PLWHA continue to experience despite the presence of ART and the need to address these problems holistically to achieve viral suppression and improve their quality of life. HCP confessed that when they compared their previous approach to practice, the holistic approach was promising due to the effect it had on PLWHA and the fulfilment they (HCP) had in being able to partner with PLWHA during care delivery.

(iv) Challenges with time taken to deliver the intervention: Among the challenges faced by HCP while delivering the intervention included the time taken to assess participants' symptoms and concerns, plan and deliver care, and the amount of paperwork (records) required to be completed. These issues were discussed at every meeting in order to find lasting solutions to them. The main concern about time has been that HCP got lost in the assessment of participants problems that they feared to stop participants even when these issues were repetitive. HCP also agreed that they tend to enjoy the conversation with participants resulting in some time loses. Both HCP and the researcher agreed that the initial assessment of participants took time because

there was a need to capture all the issues that the participant had at the first assessment. However, subsequent appointments were to review initial problems assessed as well as assess new problems and concerns that occurred after their last visit. HCP confessed that most of the time there were no new issues, but they could not stop participants from chatting with them, so they end up spending more time. Solutions discussed included prioritising the review of participants problems from last visit and any new issues that came up and respectfully told participants the researcher was waiting to have more discussion with them. This solution seemed to have worked.

The challenge about the paperwork could not be resolved completely at the time of the trial. Therefore, the researcher discussed and encouraged HCP to persevere and report all their issues directly to the researcher as these challenges were the reason for the feasibility trial, so that the issues reported would be addressed before planning a definitive trial. Overall, HCP discussed that they felt satisfied that despite the time constraint they faced while delivering the intervention, they were very content to be able to assess and manage PLWHA using available clinic resources.

6.1.7 Follow up

The CONSORT flow diagram in Figure 26 shows that no participant within each cluster was lost to follow-up. The number of participants providing data for each outcome measure at baseline and subsequent monthly follow-ups are also presented in Figure 26. Intervention compliance was high, only four participants from the intervention arm missed one session and none missed more than one. Outcome measure compliance was also high; 11.7% (n = 4 for the intervention arm and n = 3 for the control arm) of data were lost for Month 1, 2 and 3 for all outcomes, which was predominantly due to participants missing their appointments. All outcome measures were completed face to face with each participant. Participants usually saw the researcher after each intervention appointment to complete the outcome measures after receiving their respective interventions. Follow up rates are reported in Table 27 for both CECI and SHC appointments.

Table 27: Follow up rates

Time points	Outcome measures CECI n=30 n (%)	Outcome measures SHC n=30 n (%)	Whole sample n=60 n (%)
Month 1 (T1)	28(93%)	28(93%)	56(93%)
Month 2 (T2)	30(100%)	29(97%)	59(98%)
Month 3 (T3)	28(93%)	30(100%)	58(97%)

6.1.8 Intervention implementation fidelity and adherence

Implementation fidelity is how an intervention is implemented as intended, which also helps in increasing confidence in the study outcomes as being influenced by the intervention [389, 390]. There is evidence that the success of an intervention is dependent on the fidelity with which it is implemented [390, 391]. Table 28 demonstrates how CECI fidelity was implemented during the feasibility trial.

Table 28: CECI fidelity checklist

Items	What was planned	What was done
Intervention training	To deliver 5 sessions of 1hour per session per day	Delivered 3 sessions of 2hours per session for three days
Who was at the training	2 doctors, 4 nurses, 2 counsellors, 1 social worker, 2 care assistants.	1 doctor, 4 nurses, 2 counsellors, 1 social worker, 2 care assistants and 2 laboratory technicians.
Training provider	All training sessions will be delivered by the researcher (MA-O)	All training was delivered by the researcher
Mode of training	Face to face training, PowerPoint presentation, Discussions and role play	Face to face training, PowerPoint presentations, discussions and role plays.
Training resources/ materials/ certificates	To provide training on the use of holistic assessment tool and care plan with copies to practice with. To provide training certificates for HCP who attended all 3 training sessions	Holistic assessment tool and care plan were provided to record participant assessments and aid collaborative care planning HCP who attended both 2 and 3 sessions of the training were all provided with training certificates
Skill acquisition and maintenance of skills post training	To conduct twice-weekly mentorship, supervision and monitoring meetings with HCP	Twice-weekly meetings were held with HCP to supervise, mentor, and monitor HCP skills and wellbeing
Intervention delivery		
No. of CECI appointments	To have 3 CECI appointments scheduled monthly for 3 months	3 appointments of CECI was provided over 3 months with participants attending their appointments once every month
Length of each appointment	Each appointment to last between 30-45 minutes	Each appointment lasted for 30 - 61 minutes.

Ensuring that the intervention is delivered as intended	To conduct twice-weekly mentorship, supervision and monitoring meetings with HCP Completion rates of outcome measures	Twice-weekly meetings were held to assess HCP performance and challenges Outcome measure completion rates were recorded as 93%, 100% & 93% at T1, 2 & 3 respectively
Intervention receipt		
No of participants who received the intervention	N=30 participants to receive the intervention for monthly for 3 months.	N=28/30 received the intervention in month1 N=30/30 received the intervention in month 2 N=28/30 received the intervention in final month 3
Intervention acceptability	To conduct a post-trial interviews with 6-8 HCP and n=10 PLWHA to establish intervention acceptability	N=7 HCP and n=10 PLWHA were interviewed

6.2 Summary of feasibility findings

The primary outcome findings have been summarised in Table 29.

Table 29:Primary outcome findings

Primary outcomes	**Results**
Number of potential participants screened	N=83
Number of eligible potential participants	N=69
Number of participants consented and recruited into the trial	N=60
Recruitment target achieved	60 participants within 6weeks at a rate of 87%.
Proportion of participants who dropped out during the intervention delivery	No participant dropped out
Total number of intervention sessions delivered	N=3
Total number of participants present at final timepoint	58/60
Retention rate target set	80%
Retention rate target achieved	97%
Number of participants lost to follow-up	None
Adverse events recorded during the trial.	None

6.3 Outcome measures

A total of five measures (3 outcome and 2 process measures) were used during the feasibility trial of CECI. The 3 outcome measures used were APCA POS, MOS-HIV and POSITIVE OUTCOMES. These outcome measures were preferred because they assess and measure the four domains of needs (physical, psychological, social and spiritual wellbeing) that PLWHA want support with. There were 2 process measures: PPE-15 and CARE Measure which assesses and measures the process of care delivery.

6.3.1 Missing data

A total of 180 data collection appointments were offered, which could have been attended, however, 7 of these appointments were not attended, as a result there is no missing data for any outcome measure (7 missing out of a possible total of 180: 3.9% missing). Whilst the figure of 3.9% missing data is low, of this 3.9%, 4 of the 7 missing data points (57%) occurred in the intervention arm due to participants missing their appointments. Among the completed post-trial interviews, there was no missing data. All other attended data collection appointments had complete data. See Tables 30 and 31 for summaries of missing data by time point and data completeness for completed measures.

Table 30: Summary of missing data from outcome measures by timepoint and trial arm

Time points	Missing data type	Control (SHC) n=30	Intervention (CECI) n=30	Total control & intervention n=60
Month 0 (baseline)	Missed single questions	7	10	17
	Missed single questionnaire	0	0	0
	Missed all sets questionnaire	0	0	0
	Premature exit	0	0	0
	Deceased	0	0	0
Month 1	Missed single questions	0	0	0
	Missed single questionnaire	0	0	0
	Missed all sets questionnaire	2	2	4
	Premature exit	0	0	0
	Deceased	0	0	0

Month 2	Missed single questions	0	1	1
	Missed single questionnaire	0	0	0
	Missed all sets questionnaire	1	0	1
	Premature exit	0	0	0
	Deceased	0	0	0
Month 3	Missed single questions	0	1	1
	Missed single questionnaire	0	0	0
	Missed all sets questionnaire	0	2	2
	Premature exit	0	0	0
	Deceased	0	0	0

Table 31: Data completeness for completed measures by timepoint

Measures	Time point	No. of participants completing outcome measures	Total no. of items	N participants (%) with complete data	Total no. missing items	% missing items
APOS (0-35)	Baseline	60	7	60 (100%)	0	0
	T1	56	7	56 (93%)	****7	1%
	T2	59	7	59 (98%)	*7	<1%
	T3	58	7	58 (97%)	**7	<1%
MOS-HIV (0-100)	Baseline	60	35	60 (100%)	0	0
	T1	56	35	56 (93%)	****35	<1%
	T2	59	35	59 (98%)	*35	<1%
	T3	58	35	58 (97%)	**35	<1%
PPE-15 (1-55)	Baseline	60	15	60 (100%)	0	0
	T1	56	15	56 (93%)	****15	<1%
	T2	59	15	59 (98%)	*15	<1%
	T3	58	15	58 (97%)	**15	<1%
CARE Measure (1-50)	Baseline	60	10	60 (100%)	0	0
	T1	56	10	56 (93%)	****10	<1%
	T2	59	10	59 (98%)	*10	<1%
	T3	58	10	58 (97%)	**10	<1%

Positive Outcomes (1-23)	Baseline	60	23	60 (100%)	0	0
	T1	56	23	56 (93%)	****23	<1%
	T2	59	23	59 (98%)	*23	<1%
	T3	58	23	58 (97%)	**23	<1%

****7 four persons missed seven items on the APCA POS, 35 items on MOS-HIV, 15 items on PPE-15, 10 items on CARE Measure and 23 items on Positive outcomes HIV PROM at T1. *7 one person missed seven items on APCA POS, 35 items on MOS-HIV, 15 items on PPE-15, 10 items on CARE Measure and 23 items on Positive outcomes HIV PROM at T2; **7 two persons missed seven items on APCA POS, 35 items on MOS-HIV, 15 items on PPE-15, 10 items on CARE Measure and 23 items on Positive outcomes HIV PROM at T3.

6.3.2 Outcome measures and time to complete

Sixty participants completed the baseline data collection, fifty-six completed the follow-up outcome measures at time point 1 and then fifty-nine and fifty-eight participants completed the follow-up data at time point 2 and time point 3 respectively. For the five measures used, the APCA POS, PPE-15 and Positive Outcomes lower scores indicate better outcomes, whereas the MOS-HIV and CARE Measure higher scores indicate better outcome. Participants took approximately 30 to 45 minutes to complete all the outcome measures (those who completed it without any assistance with reading and explaining what each item on the measure meant used 30 minutes and those who required assistance spent 45 minutes).

6.3.2.1 Outcome measure data

The outcome data collected focused on the physical, psychological, social and spiritual wellbeing of PLWHA. The mean and standard deviation for the outcome measures (APCA POS, MOS-HIV and Positive Outcomes) for both the control and intervention arms are reported in Table 32 with the corresponding change scores in Table 33. Data is normally distributed for the mean and standard deviation.

Table 32: Mean scores with corresponding standard deviations

	Control (SHC)				Intervention (CECI)			
Outcome measures	**Baseline mean (SD) n=30**	**Time 1 mean (SD) n=28**	**Time 2 mean (SD) n=29**	**Time 3 Mean (SD) n=30**	**Baseline Mean (SD) n=30**	**Time 1 mean (SD) n=28**	**Time 2 mean (SD) n=30**	**Time 3 mean (SD) n=28**
APCA POS[1]	12.0 (4.1)	13.0 (3.8)	16.0 (2.0)	14 (1.7)	14.0 (2.9)	11.0 (1.7)	9.0 (1.2)	9.0 (1.5)
MOS-HIV[2]	30.1 (9.2)	25.5 (13.6)	19.5 (12.2)	53.2 (7.8)	26.6 (7.5)	66.4 (6.5)	74.0 (4.0)	83.0 (2.9)
Positive Outcomes[1]	30.0 (5.2)	28.0 (6.5)	38.0 (4.5)	30.0 (3.9)	26.0 (8.1)	23.0 (6.0)	18.0 (3.8)	16.0 (3.8)

Table 33: Change scores with potential effect sizes and confident intervals estimated at Time 3

	Control (SHC)			Intervention (CECI)			
Outcome measures	**Time 1 mean (SD) n=28**	**Time 2 mean (SD) n=29**	**Time 3 Mean (SD) n=30**	**Time 1 mean (SD) n=28**	**Time 2 mean (SD) n=30**	**Time 3 mean (SD) n=28**	**Potential Effect size [95% CI] of the intervention at Time 3**
APCA POS[1]	1.0 (5.6)	4.0 (4.6)	2.0 (4.4)	-3.0 (3.4)	-5.0 (3.1)	-5.0 (3.3)	0.7 [0.17 to 1.23]
MOS-HIV[2]	-4.6 (16.42)	-10.6 (15.3)	23.1 (12.1)	39.8 (9.9)	47.4 (8.5)	56.4 (8.0)	0.7 [0.17 to 1.23]
Positive Outcomes[1]	-2.0 (8.3)	8.0 (6.9)	0.0 (6.5)	-3.0 (10.1)	-8.0 (8.9)	-10.0 (8.9)	0.7 [0.17 to 1.23]

[1] Lower scores= better outcomes
[2] Higher scores= better outcomes

6.3.2.2 Process (experience of care) measure data

The process measure captured data on the approach to care delivery, communication, relationship with HCP, patient involvement in care decisions and the empathy felt by PLWHA at care delivery. Data is normally distributed for the mean and standard deviation, mean and standard deviation for the process measures (CARE Measure and PPE-15) for both study arms are reported in Table 34 with the corresponding change scores in Table 35.

Table 34: Mean scores with corresponding standard deviations for the process measures

	Control ((SHC)				Intervention (CECI)			
Process measures	**Baseline mean (SD) n=30**	**Time 1 mean (SD) n=28**	**Time 2 mean (SD) n=29**	**Time 3 Mean (SD) n=30**	**Baseline Mean (SD) n=30**	**Time 1 mean (SD) n=28**	**Time 2 mean (SD) n=30**	**Time 3 mean (SD) n=28**
CAREM[2]	5.0 (3.3)	3.0 (2.8)	5.0 (1.1)	7.0 (1.6)	5.0 (3.3)	23.0 (3.1)	27.0 (2.2)	33.0 (1.4)
PPE-15 [1]	31.0 (1.9)	32.0 (2.1)	33.0 (1.2)	32.0 (1.5)	30.0 (2.7)	26.0 (1.9)	24.0 (2.7)	24.0 (2.4)

Table 35: Change scores with potential effect sizes and confident intervals

	Control (SHC)			Intervention (CECI)			
Process measures	**Time 1 mean (SD) n=28**	**Time 2 mean (SD) n=29**	**Time 3 Mean (SD) n=30**	**Time 1 mean (SD) n=28**	**Time 2 mean (SD) N=30**	**Time 3 mean (SD) n=28**	**Potential Effect size [95% CI] of the intervention at Time 3**
CAREM[2]	-2.0 (4.3)	0.0 (3.5)	2.0 (3.7)	18.0 (4.5)	22.0 (4.0)	28.0 (3.6)	1.0 [0.45 to 1.55]
PPE-15 [1]	1.0 (2.8)	2.0 (2.2)	1.0 (2.4)	-4.0 (3.3)	-6.0 (3.8)	-4.0 (3.6)	0.8 [0.27 to 1.31]

[1] Lower scores= better outcomes
[2] Higher scores= better outcomes

6.3.3 Potential effect sizes

An effect size is a quantitative measure of the difference between two groups. An exploratory analysis conducted to estimate the potential effect size of the CECI intervention described the results in terms of magnitude as the p-value showed whether the intervention was effective statistically, and the effect size explains the degree of the effect on participants involved [392]. The potential effect sizes were estimated using standardised mean difference [393], and reported using Cohen's d effect size ranges of small (0.2), medium (0.5) and large (0.8) effects. The corresponding confidence intervals (CI) have also been reported. The potential effect sizes ranged from 0.7 to 1, however with reference to the CI, the CECI intervention achieved small to medium potential effects, these are reported in Table 36.

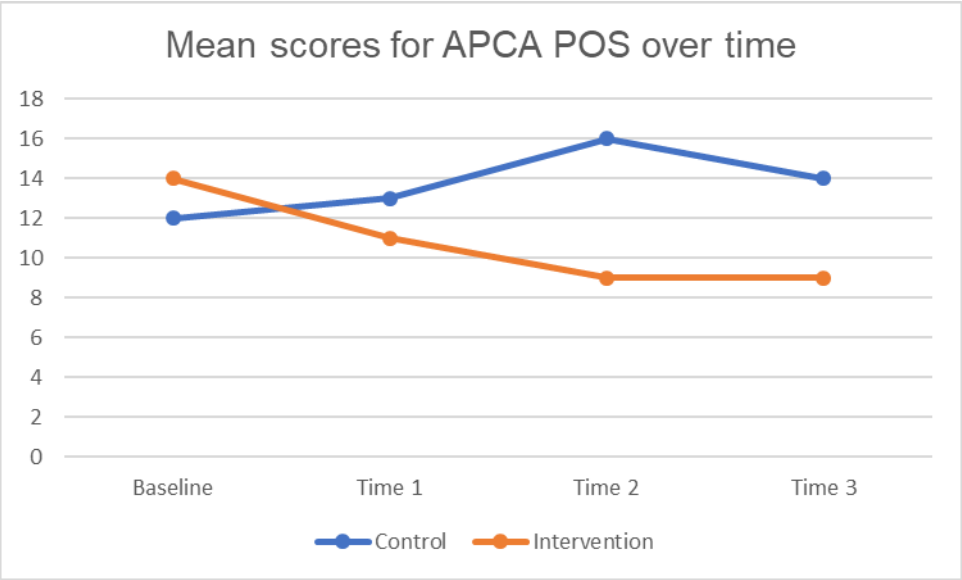
Table 36: Potential effect size estimates by measure

Measure	**Partial Eta Squared statistics for Potential Effect size (ηp^2)**	**95% CI**	**p-value**
APOS	0.7	[0.17 to 1.23]	p<0.001
MOS-HIV	0.7	[0.17 to 1.23]	p<0.001
CAREM	1.0	[0.45 to 1.55]	p<0.001
PPE-15	0.8	[0.27 to 1.31]	p<0.001
PO	0.7	[0.17 to 1.23]	p<0.001

6.3.4 Comparison of outcome measure mean scores for control and intervention arms

Outcome measure mean scores recorded for the control and intervention arms have been compared and plotted in Figures 27, 28 and 29 to identify any change over time.

Figure 27 compared mean scores for APCA POS obtained over time from baseline to final timepoint 3 for both control and intervention arms. The APCA POS measured physical and psychological symptoms, spiritual, practical and emotional concerns and psychosocial needs. As observed in Figure 27, the control arm recorded a mean score of 12 at Baseline, which increased to 13 and 16 at Times 1 and 2, then decreased to 14 at Time 3. Comparatively, the intervention arm also recorded a mean score of 14 at Baseline, which decreased to 11 at Time 1, and further decreased to 9 at Time 2 and remained the same at Time 3. Since lower APCA POS scores indicate better outcomes, this implied that from Time 1 to Time 2, the symptoms and concerns of participants in the control arm worsened but began to improve from Time 2 to Time 3. Likewise, participants in the intervention arm experienced a gradual improvement in their symptoms and concerns from Time 1 to Time 2 however, there was no further improvement at Time 3, as the mean score did not change from Time 2.

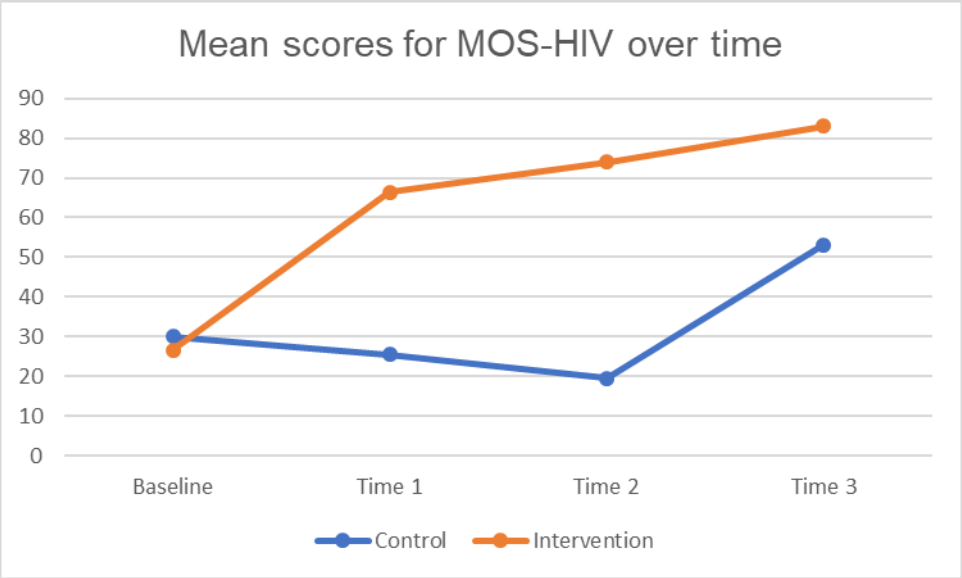


Higher APCA POS scores indicate greater symptom burden

Figure 27: APCA POS mean scores plotted for control and intervention arms

Figure 28 compared mean scores for MOS-HIV obtained for the control and intervention arms from Baseline to final timepoint 3. The MOS-HIV measured pain, general health perception, mental health, health distress and vitality in addition to role, physical, cognitive and social functioning. As shown in Figure 28, participants in the control arm recorded a mean score of 30.1 at Baseline, which decreased to 25.5 at Time 1and further

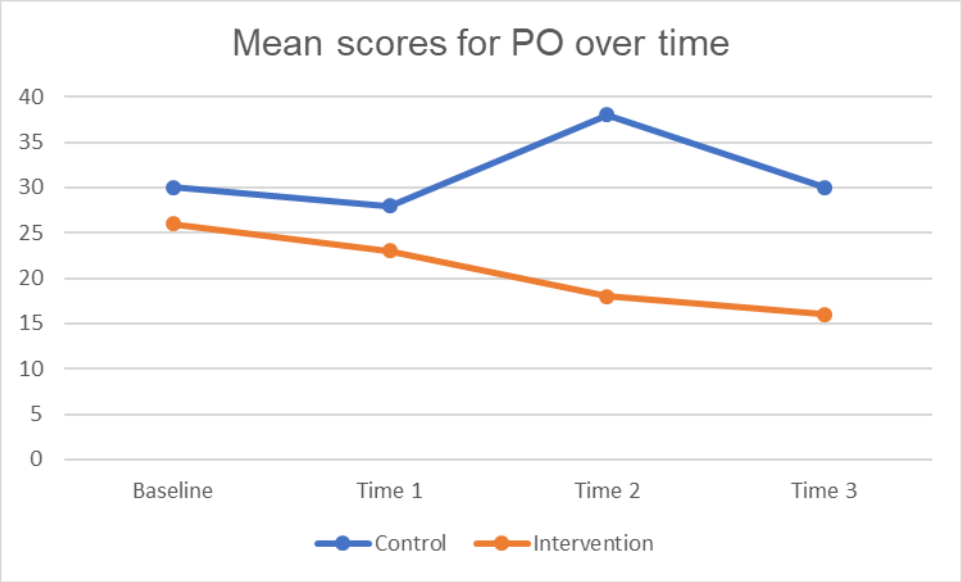
decreased to 19.5 at Time 2 and a sharply increased to 53.2 at Time 3. Relatively, the intervention arm recorded a mean score of 26.6 at Baseline, which sharply increased to 66.4 at Time 1, and a steadily increased to 74 and 83 at Times 2 and 3 respectively. As higher MOS-HIV scores indicates better outcomes, these results indicate that participants in the control arm experienced worsening symptoms and concerns from Time 1 to Time 2, but from Time 2 to Time 3, they experienced significant improvement in their wellbeing. Similarly, participants in the intervention arm experienced steady improvement in symptoms and concerns from Time 1 through to Time 3.



Lower MOS-HIV scores indicate greater symptom burden

Figure 28: MOS-HIV mean scores plotted for control and intervention arms

Figure 29 also compared mean scores for Positive Outcomes obtained from Baseline to final timepoint 3 for both the control and the intervention arms. The Positive Outcomes measured physical and emotional wellbeing, home and social life including sex and intimate relationships. As indicated, the control arm recorded a mean score of 30 at Baseline which slightly decreased to 28 at Time 1, then a sharply increased to 38 at Time to and significantly decreased to 30 (back to baseline score). In contrast, participants in the intervention arm recorded a mean score of 26 at Baseline, which marginally decreased to 23, 18 and 16 at Times 1, 2 and 3 respectively. As lower Positive Outcomes scores indicate better outcomes, these results suggest that symptoms and wellbeing of participants in the control arm worsened from Time 1 to Time 2 but began to improve from Time 2 to Time 3. Comparatively, symptoms and wellbeing of participants in the intervention arm improved steadily from Time 1 through to Time 3.



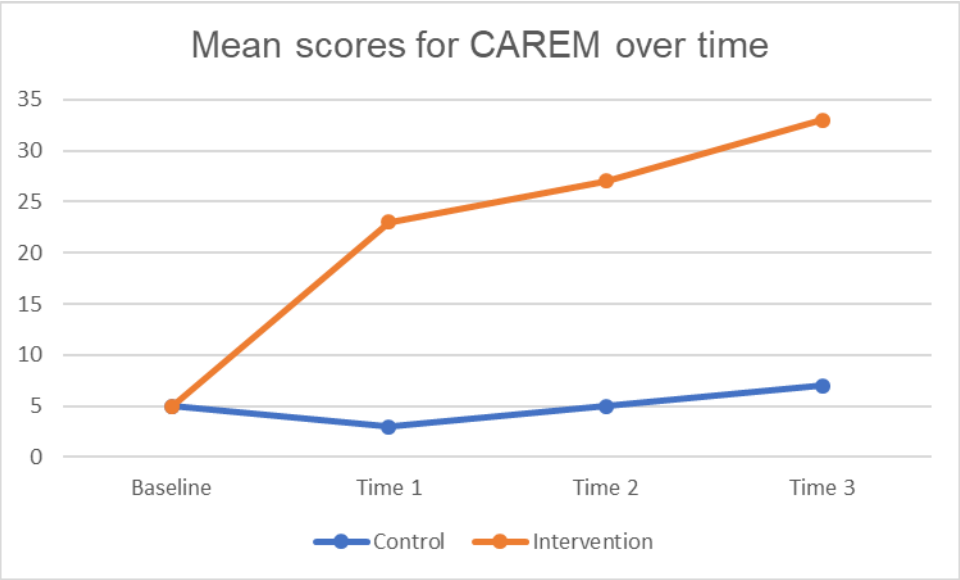
Higher PO scores indicate greater symptom burden

Figure 29: POSITIVE OUTCOMES mean scores plotted for control and intervention arms

6.3.4.1 Comparison of process measure mean scores for control and intervention arms

Process measure mean scores recorded for the control and intervention arms have been compared and plotted in Figures 30 and 31 respectively, to note any change over time.

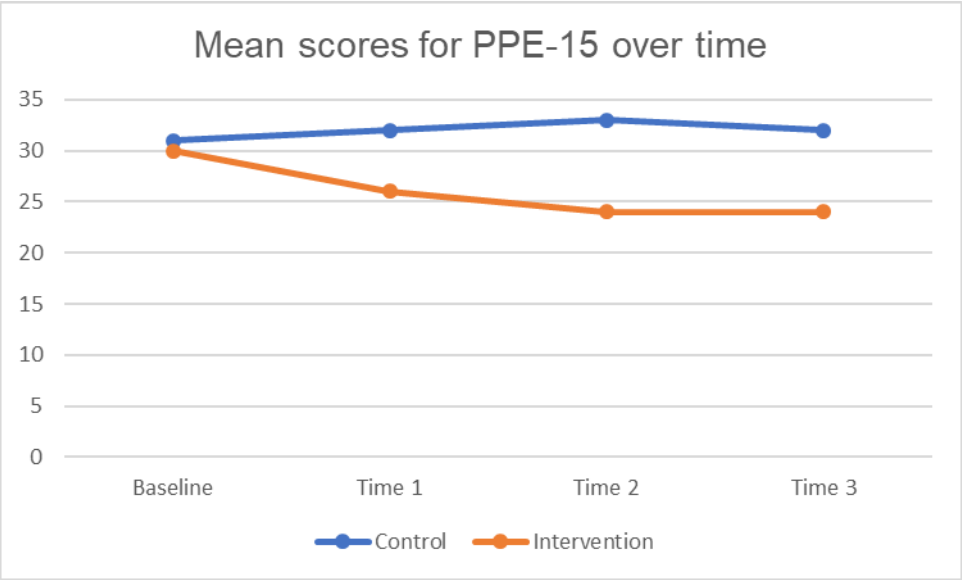
Figure 30 compared mean scores for CAREM obtained from Baseline to final timepoint 3 for control and intervention arms. The CAREM measured the amount of empathy that participants felt they had experienced during care delivery. As observed, the control arm recorded a mean score of 5 at Baseline, which decreased slightly to 3 at Time 1, then steadily increased to 5 and 7 at Times 2 and 3 respectively. On the other hand, participants in the intervention arm who recorded the same mean score of 5 at Baseline, drastically increased to 23 at Time 1 and steadily increased to 27 and 33 at Times 2 and 3 respectively. Since high CAREM scores indicate better outcomes, these scores meant that participants in the control arm experienced less amount of empathy compared to participants in the intervention arm who experienced good amount of empathy during care delivery, which increased steadily from T1 to Time 2 and significantly from Time 2 to Time 3.



Higher CAREM scores indicate better care experience

Figure 30: CAREM mean scores plotted for control and intervention arms

Figure 31 compared the PPE-15 mean scores obtained from Baseline to final timepoint 3 for control and intervention arms. The PPE-15 measured patient experience along the domains of communication, emotions, short-term outcomes, barriers and relationship with HCP. Participants in the control arm recorded a mean score of 31 at Baseline, which increased to 32 and 33 at Times 1 and 2, then decreased to 32 at Time 3. Likewise, participants in the intervention arm recorded a mean score of 30 at Baseline, which decreased to 26 at Time 1, and further decreased to 24 at Time 2 and remained the same for Time 3. Lower PPE-15 scores indicate better outcomes therefore, these scores implied that participants in the control arm did not have as good experience of care as compared to those in the intervention arm who had good experience with the care they received from Time 1 to Time 2 however, there was no further change at Time 3.



Lower PPE-15 scores indicate better care experience

Figure 31: PPE-15 mean scores plotted for control and intervention arms

The next section (**6.4**) reports on the post-trail qualitative interview findings.

6.4 Post-trial qualitative interview findings on CECI acceptability

A qualitative exploration in the form of semi-structured exit interviews was used as part of the process evaluation to understand the CECI intervention outcomes from participants' perspectives. The CECI participants (PLWHA and HCP) were invited to share their views, experiences and outcome with the intervention.

6.4.1 Sample characteristics

Participants were purposively recruited for the post-trial interview approximately 2 weeks after they had exited from the quantitative component of the feasibility cRCT. The sample characteristics are reported in Table 37 with reference to the sample for the entire feasibility cRCT dataset used in the quantitative data analysis so as to allow for comparability assessment.

Table 37:Sample characteristics for the entire feasibility cRCT and the post-trial interviews

Characteristics	**Feasibility cRCT n=60**		**Post-trial interviews n=20**	
	N (%)	**Mean (SD)**	**N (%)**	**Mean (SD)**
Age (years)		37.75 (10.94)		43.1 (12.68)
Gender: female	31 (51.7)		10 (50)	
Sexual orientation Heterosexual MSM WSW Bisexual Missing	 44 (73.3) 8 (13.3) 1 (1.7) 5 (8.3) 2 (3.3)		 16 (80) 3 (15) 1 (5) 0 0	
Has a partner (yes)	39 (65.0)		11 (55)	
Number of children		1.72 (1.49)		1.85 (1.50)
Number of financial dependants		2.05 (2.12)		1.75 (1.77)
Education No school Primary Secondary Diploma ≥Degree	 3 (5.0) 6 (10.0) 22 (36.7) 17 (28.3) 12 (20.0)		 1 (5) 1 (5) 9 (45) 7 (35) 2 (10)	
Employment status White Collar Worker Shop keeper Skilled Worker Unemployed Missing	 7 (11.7) 35 (58.3) 1 (1.7) 16 (26.7) 1 91.7)		 1 (5) 13 (65) 6 (30)	

CD4 count (cells/mm^3)		365.12 (139.68)		445.45 (203.34)
WHO clinical stage Stage 1 Stage 2 Stage 3 Stage 4 Missing	 4 (6.7) 45 (75.0) 8 (13.3) 1 (1.7) 2 (3.3)		 3 (15) 15 (75) 1 (5) 1 (5)	

As observed in Table 37, the sub-sample used for the post-trial interviews appeared similar to the sample used for the feasibility cRCT in terms of clinical and demographic characteristics. Table 38 reports on the sample characteristics of HCP who delivered the intervention. The sampling frame for the post-trial interviews was achieved.

Table 38: Sample characteristics for HCP who were interviewed in the CECI arm

Participant ID	Age	Gender	Role
PTQIS HCP 1	38	M	Doctor
PTQIS HCP 2	38	F	Counsellor
PTQIS HCP 3	28	F	Nurse
PTQIS HCP 4	33	M	Counsellor
PTQIS HCP 5	25	M	Nurse
PTQIS HCP 6	27	F	Social worker
PTQIS HCP 7	26	F	Nurse

6.4.2 Coding framework

Participants wellbeing prior to entering the feasibility cRCT, during the trial and their present wellbeing were explored during the post-trial interviews. Six major themes emerged from the thematic analysis of the post-trial interview data: (i) *relevance of intervention training*, (ii) *intervention delivery, experience and acceptability*, (iii) *holistic care and quality of life*, (iv) *care communication and partnership*, (v) *time burden and service limitations,* and (vi) *therapeutic benefits of participating in the study*. These themes mainly focused on participants experience during and immediately after exiting the trial, which are described in turn, and illustrative quotes with unique identifiers are provided to support the themes.

6.4.2.1 Relevance of intervention training

Conducting the CECI intervention training with the team of HCP helped to foster collective responsibility for implementation of PCC and strengthened peer support and mutual learning. This was praised by HCP as it addressed relevant issues that have lost priority in HIV care delivery:

> “The intervention training is good as it raised relevant areas of care that is so important to our clients, but these areas are not prioritised. So, I am very glad that all our staff were present at the training and we can all look at our service delivery.” (PTQIS HCP 6, age 27, intervention).

Moreover, the use of role-play during the intervention training has been highlighted as useful in explaining the concept of person-centred and holistic care to HCP:

> “What I found useful about the training session was the materials used during the training. For example, the use of role play was excellent as it helped explain the whole concept of holistic care and the person-centred approach. Every aspect of the training was useful.” (PTQIS HCP 4, age 33, intervention).

Focusing the training on using the person-centred approach to care for PLWHA improved HCP’s understanding of the concept, which helped them to communicate effectively with patients when assessing their needs:

> “My view is that it was good the training focused on these aspects of care because it helped me to appreciate and understand the person-centred approach to care. In addition to how to communicate appropriately with my clients in order to understand them and assess their needs.” (PTQIS HCP 7, age 26, intervention).

This has contributed to reflective practice among HCP who expressed fulfilment and satisfaction at the results of their collaborative care practice with PLWHA:

> “This training has helped me to take a second look at the way I practice and to see the difference the holistic approach makes in the care I deliver. Because looking back at the way I used to practice compared to now, I think that this holistic approach is very promising. This is because of the effect it had on our clients, the fulfilment I get being able to partner with my clients and coming up with a care decision that we both agree

on and seeing them for this past 3 months more enthusiastic about their care its really satisfying." (PTQIS HCP 1, age 38, intervention).

HCP wished the training had lasted for longer but acknowledged that the nature of the clinic could not allow that:

"The duration of the training was okay although I would have wished that a whole day could have been dedicated for such important training to enable us to participate in some group work and discuss the domains of the training deeper. However, this was not possible considering the nature of the clinic." (PTQIS HCP 5, age 25, intervention).

6.4.2.2 Intervention experience and acceptability

Participants in the intervention arm revealed acceptability and perceived benefits of the intervention with many participants reporting experiencing difference in the care they received. The difference in the care experienced included HCP approach to symptom assessment and involvement of PLWHA in planning their care:

"The way staff assessed my problems step by step wanting to know all about me and my life outside HIV and more importantly, my involvement in care and staff planning my care with me was the main thing that helped me most." (PTQI PLWHA 7, age 28, intervention).

HCP had to encourage participants to contribute to their care plan as they initially thought it was not their responsibility to make decisions about their care, as has been the normal practice:

"Generally, clients are very happy about being part of the decisions being made about their care. Initially, they were not sure if they should really be part of their care, so some kept saying 'this is your job why are you asking me?' But when I explain that I need their contribution in order to support them better, they gradually started making meaningful contribution to their care plan" (PTQIS HCP 1, age 38).

The importance of involving participants in their care decisions was highlighted by HCP who resolved that they would endeavour to involve participants in making decisions about their care:

> "I have come to see the real difference in involving my clients in care decisions compared to not involving them at all because they became very enthusiastic and were giving a lot of suggestions about how they want to be supported. Therefore, what I would do differently is to always ensure that I do not make any care decision without my client's involvement. Also, I would modify the way I communicate with my clients in the sense that I will be more person-centred." (PTQIS HCP 6, age 27, intervention)

Participants also noted that they felt valued and respected by HCP who took their time to ask them of their opinion about the care they receive:

> "Because all of a sudden, it felt that I was so important that my opinion about my care mattered to staff and they want me to contribute to how I should be supported. I can't explain why but I think it is because staff were patient and they wanted me to be part of the care as I have never seen them like this before." (PTQI PLWHA 9, age 39, intervention).

This quote is supported by HCP who confirmed that participants' self-worth had improved as a result of their involvement in their care:

> "Most of my client felt respected and important with the idea that they are invited to plan their care and were empowered by the decision. This opportunity also made my clients make meaningful contributions to their care." (PTQIS HCP 7, age 26, intervention).

HCP on the other hand, described the intervention as opening their eyes to the broader challenges faced by PLWH, which they felt unprepared to address:

> "Delivering this enhanced care is like an eye opener for me personally because it helped me to understand the daily challenges that our clients go through in the areas of taking their medication, spiritual issues and the enormous psychological issues that

we do not get to know about our clients because we don't ask them about it." (PTQIS HCP 4, age 33 intervention).

Moreover, others described their initial experience of delivering the intervention, including challenges faced. However, they praised the weekly support received during the intervention delivery that helped to overcome some of the challenges:

"The delivery of the enhanced care intervention was a bit challenging at the start as it was the first time, we have had to use this holistic approach, Some of these challenges were the amount of paper work that we needed to complete for one client and another was when the clients come in with complex issues. However, it became easy due to the continues supervision support received during the weekly meetings and we were able to adjust and get over the challenges we had." (PTQIS HCP 2, age 38, intervention).

6.4.2.3 Holistic care/ person-centred care and quality of life

HCP described their understanding of person-centred/ holistic care as using the values and preferences of individuals to guide care delivery including addressing their physical, psychological, social and spiritual needs:

"My understanding of person-centeredness or holistic care is that there are four types of need for all persons including our clients, these are the physical needs, psychological needs, social and spiritual needs. Apart from that, people may also have different preferences for how they want their care to be delivered and their beliefs and values, so when we consider all these aspects of individuals who come to seek care and allow it to guide the care delivery then we can say we are delivering a holistic care." (PTQIS HCP 1, age 38, intervention).

PLWHA described a novel experience of care that focused on them as individuals and considered them as partners in their own care:

> “This new approach that staff are using at the clinic has really make me look forward to going to work and at work I am very much relaxed and I can’t explain it but it’s more like being satisfied with my life, it is as if a burden has been lifted of my head, I now smile more and am more chatty.” (PTQI PLWHA 2, age 40, intervention).

This improvement in work-related quality of life was reiterated by another participant who felt able to work without having to think or worry about HIV:

> “I am now able to go to work and go about my daily activities without any guilt or worry about my HIV or what people think of me. Life is much much better now because I am able to talk to staff at the clinic about anything that worries me. Because staff are now interested in my problems and I am also happy to share it with staff each time I have a problem.” (PTQI PLWHA 8, age 26, intervention).

Participants also remarked that they were able to live a normal life with reduced level of worry although unable to disclose HIV status to family:

> “I would not say I have stopped worrying completely but the rate at which I used to worry has reduced greatly. I tried to live a normal life among my family and community the only thing I have not been able to do is to disclose my status to my family or friends but even that I am much happier and relaxed now.” (PTQI PLWHA 1, age 41, intervention).

The length of questionnaires was deemed to be acceptable and the similarity of questionnaires were also deemed to be appropriate. One participant had felt that there was some repetition between questions in outcome measures as some measures had asked about experiences over last 3 days (APCA POS) and others over last 30 days (MOS-HIV):

> “Most of the questions were easier to answer and short, one was quiet long. Also, some of the questions were similar to each other so I kept repeating myself. But the difference is that some of the questions were asking for 3 days experience and others were asking for 30 days so that’s ok.” (PTQI PLWHA 5, age 52, intervention).

Participants described feeling good about being able to discuss the outcomes of care and felt positive about that:

> "It was as if I was giving an account of what has been happening in the clinic and about my life but it felt really good because after receiving care from clinic staff then I come and talk to the investigator who also takes time to ask me questions about my life and how am coping with living with HIV, that was great." (PTQI PLWHA 10, age 31, intervention).

6.4.2.4 Care communication and partnership

The importance of communication was raised by participants who felt that their level of communication with HCP had improved to the point where they could speak their mind:

> "Staff are now more welcoming, politer and spending more time discussing my problems with me and allows me to also speak my mind and to share my opinion which was not the case before." (PTQI PLWHA 7, age 40, intervention).

HCP also acknowledged the importance of effective communication in order to know and understand what matters to participants. This was demonstrated by HCP's interest in the problems experienced by PLWHA alongside their HIV disease, as well as involving them in planning their care:

> "Therefore, my understanding of the basis for this intervention is that it focuses on the 'person' receiving the care and what matters to him/her most. And to know what matters to this person, I must communicate with the person well in order to know what is most important for that person." (PTQIS HCP 1, age 38, intervention).

Participants recognised the difference in the way HCP communicated with them and have related it to HCPs' patience in wanting to know them better:

> “Yes, so much change in the way staff talked with me, the way they asked me questions about my health and also asked me what matters to me about my care. It was like staff were not in a hurry to see the next patient, they were very patient and wanting to know all about me.” (PTQI PLWHA 8, age 26, intervention).

Participants also praised the effect of good communication as it made them felt better and able to talk about their problems with HCP:

> “Now I feel much better because I don’t have to keep quiet about my symptoms of pain or any other physical problems because if I don’t talk about them staff will keep on asking me about my physical health. So now staff always ask me about pain and other problems which I always discuss them with staff and together we decide what will help me better.” (PTQI PLWHA 6, age 28, intervention).

One HCP remarked that the training received on the intervention helped improved her communicative skills which has led to the discovery of her counselling abilities:

> “I didn’t know that I can be a good counsellor until this training on the intervention. Now I am able to communicate well with my clients, ask them question that will make them talk about themselves and the issues bordering them. This intervention has also empowered me to be able to assess and manage my clients using the available clinic resources, it is really exciting you know. And seeing my client have a lot to say about their care was to me the icing on the cake”. (PTQIS HCP 4, age 33, intervention).

6.4.2.5 Time burden and service limitation

The time taken to deliver the intervention and service limitation were among the challenges discussed. HCP were concerned that although they felt fulfilled to be able to deliver holistic care the intervention delivery process was time consuming:

> “My only concern is that the process of care delivery is time consuming and sometimes you get lost in your client’s concerns. However, I feel fulfilled that I am able to assess

and manage clients' needs holistically which I could not do previously." (PTQIS HCP 2, age 38, intervention).

Both PLWHA and HCP express concerns about service limitations in terms of addressing complex psychosocial needs, as PLWHA would rather have all services delivered at the clinic where they usually receive care. HCP also wished the clinic could provide all services as PLWHA are reluctant to attend other clinics when referred for fear of discrimination:

"Yes, when staff did the step by step assessment when planning my care they will say some of my problems unless they refer me to social welfare or a psychologist and I wish that this does not happen. This because I just want my care to be at this clinic and I don't want to go anywhere for these extra care or assessment. I mean can the social welfare person or the psychologist come to the clinic instead of me going to them?" (PTQI PLWHA 10, age 39, intervention).

"I wish we can be able to provide all other services that our clients will require so that we are sure they are really being supported. Because from past experience, if we refer them to access other services they hardly go for the fear of discrimination." (PTQIS HCP 4, age 33, intervention).

6.4.2.6 Therapeutic benefits of participating in the study

The experience of participants in the control arm was explored to determine if there were other benefits of participating in the feasibility cRCT beyond the benefits derived from the intervention. PLWHA in the control arm described their experience of answering questions from the researcher as a source of motivation to attend the clinic:

"My experience of care for the past 3 months has been good and a bit different from what am used to in the sense that someone is always following up on me asking me questions about my care and every aspect of my life which I think is quite nice because nobody has ever done that for me before. And I must say the thought of knowing that when I come someone will have time to ask me several questions all about my health

was my motivation to come because sometimes you only need someone to talk to and you feel better." (PTQIC PLWHA 3, age 34, control).

This assertion was reiterated by other participants who looked forward to coming to the clinic because they know that the researcher was expecting them:

"The fact that someone is always sitting at the clinic waiting for me to come and all the person wants to know is how I have been over the past month was what really helped me. Because sometimes am coming to the clinic and I don't really know what to expect but this time I actually look forward to coming because I know someone is actually expecting me." (PTQIC PLWHA 3, age 29, control).

Participants also expressed their thoughts on the completion of the outcome measures and shared similar feelings as participants in the intervention, that some of the questions were repetitive as some of the outcome measures asked about experience over 3 days (APCA POS) and others over 4 weeks (Positive Outcomes), and were pleased about the process measure question on their involvement in their care decisions (PPE-15):

"Initially I felt it was too much because some of the questions were repeating but I needed to provide the answers even if am just repeating myself. But the difference is some questions asked about your experience for the past 3days whiles others asked for 4 weeks so I guess there is a balance. The questions about 'do you want to be involved in your care'? and whether doctors or nurses discuss care decisions was very good questions." (PTQIC PLWHA 7, age 47, control).

Moreover, participants found answering the outcome measure questions easy although they required clarification to the APCA POS question on 'peace' and 'life worthwhile':

"Most of the questions were easy to answer but there were some questions that I needed more explanation on for better understanding before I could answer, say questions like are you at peace? And is life worthwhile?" (PTQIC PLWHA 9, age 26, control).

6.4.3 Summary of post-trial interview findings

Overall the intervention was acceptable across PLWHA and HCP who were extremely positive about the intervention and particularly the involvement of PLWHA in their care decisions, which they had found incredibly useful. PLWHA and HCP felt that the intervention improved their wellbeing and their ability to deliver person-centred care respectively. Moreover, PLWHA were pleased that the intervention delivery was more of a partnership between them and HCP where all their symptoms and concerns were collaboratively assessed, planned and delivered with their involvement. PLWHA felt respected and valued by the intervention delivery process as HCP included them in their care delivery, and most importantly that their concerns were addressed on their terms. HCP also revealed that the intervention opened their eyes to the distressing symptoms experienced by PLWHA that they lost sight of because they were not assessed, in addition to improving their communicative skills for holistic assessment. There were few reported challenges regarding the time required to deliver the intervention and service limitation for the management of psychosocial needs when assessed. These challenges have been noted at areas of improvement for the intervention in preparation towards a future definitive trial.

Findings also indicate that none of the participants found the completion of the outcome measures burdensome although some participants required some assistance in the form of reading the questions and the responses out for them to provide their preferred response to each question. The APCA POS, MOS-HIV, PPE-15, CARE Measure and Positive Outcomes were observed as being feasible. The small sample size prevents a definitive conclusion regarding the most appropriate primary outcome measure. Although it is not advisable to assess for an effect in a feasibility study due to it being underpowered [394], our findings nonetheless provide some information to inform the selection of primary outcome measures and timing for a future definitive trial.

As reported in the post-trial interview findings, participants found some of the questions repetitive although they at the same acknowledged that some of these measures asked for experiences over 3 days (APCA POS), 30 days (MOS-HIV) and 4 weeks (Positive Outcomes). This information is very crucial in making decisions about outcome measure selection and the possibility of opting for a trial index in a future definitive trial. Participants seemed to have no issues with the process measures (PPE-15 and CARE Measure), which will be an important consideration in a future definitive trial the process measures will remain unchanged.

In conclusion, the CECI intervention was implemented according to how the logic model intended it starting from HCP training through outcome data assessment, and all the recruitment and retention targets set have all been achieved.

Chapter 7 Discussion

7.1 Summary of main findings

UNAIDS set an ambitious '90-90-90 targets'; aiming to diagnose 90% of all HIV positive people, provide ART for 90% of those diagnosed and achieve viral suppression for 90% of those treated, by 2020 [74]. Of these targets, it has been estimated that 79% knew their HIV status, 78% were accessing treatment and 86% of those accessing treatment were virally supressed as at 2018 [49]. Although UNAIDS has emphasised the importance of person-centred are (PCC) for PLWHA in achieving the 90-90-90 targets [74], greater attention has been paid to HIV clinical management at the expense of broader psychological, social and spiritual concerns that persist despite treatment advances [5, 8, 106] and impact on their quality of life. HIV has become a chronic condition that requires persistent clinical and PCC [395] to improve retention in care in order to end the epidemic. Lazarus and colleagues also proposed adding a 'fourth 90' to the UNAIDS targets to ensure that 90% of people who achieve viral suppression also have good health-related quality of life [396]. The author argued that good health-related quality of life for PLWHA requires attention to be focused comorbidities and self-perceived quality of life. However, a systematic review conducted in Phase 1 of this thesis revealed that evidence for PCC in HIV management is weak despite global policy push.

To address this evidence gap, this thesis conducted qualitative interviews with PLWHA and HCP in community HIV management in Ghana to understand what PCC means to them and what outcomes matter to PLWHA. The interview findings revealed that PLWHA wants to be involved in their care decisions and for care to address what mattered to them. HCP also express a lack of skills to undertake holistic assessment and to practice PCC. These findings were mapped onto a PCC theory in an expert intervention development workshop. An evidence-based theoretically driven PCC intervention was developed, which was tested in a feasibility cluster (2 clusters) randomised controlled trial (cRCT) with a post-trial qualitative exit interview. This intervention and the study design were found to be both feasible to deliver and acceptable to PLWHA and HCP. Training on the intervention was well received by HCP who felt equipped with skills to carry out holistic assessment and to practice PCC. Likewise, PLWHA felt satisfied about their involvement in making decisions about their own care and their symptoms and concerns being assessed and addressed holistically using PCC. This PCC intervention seems to have potential effectiveness and a priori feasibility criteria were met.

These findings are novel as this is the first time a person-centred intervention has been developed and tested in HIV population and adds important new evidence to understand the potential benefits of person-centred interventions in PLWHA and are worthy of further investigation in a future definitive trial.

7.2 Study aim

The aim of this thesis was to develop a community-based enhanced care intervention (CECI) to improve person-centred outcomes for people living with HIV/AIDS and to test the feasibility of a cluster randomised controlled trial in terms of participant recruitment and retention, and intervention delivery.

The MRC guidance for developing and evaluating complex intervention was used to underpin the methodological approach. The CECI intervention was developed after conducting a systematic review to identify and appraise the evidence for person-centred models of community HIV care and qualitative interviews with stakeholders (PLWHA and HCP). This person-centred intervention consisted of the HCP training, holistic assessment of symptoms and concerns of PLWHA, collaborative care planning and delivery and twice weekly supervision meetings with HCP. This training was focused on person-centred care, communication, holistic approach to symptom and concerns assessment in the domains of physical, psychological, social and spiritual wellbeing and collaborative care delivery. This formed the Development stage of the MRC guidance.

7.3 Summary of objectives

7.3.1 Objective 1 (Systematic review of PCC models of community HIV management)

Objective one aimed to identify and appraise the evidence for person-centred models of community HIV management delivered or led by HCP, and to assess their impact on outcomes for PLWHA. The PCC definition adopted for this systematic review and the entire study was one described as care ‘dedicated to the promotion of health as a state of physical, mental, sociocultural, and spiritual well-being, as well as to the reduction of disease, and founded on mutual respect for the dignity and responsibility of each individual person’ [146].

A descriptive analysis of 5 PCC models of HIV management were conducted. PCC models of care delivered alongside HIV clinical management were found to be effective in improving PCC components such as physical, psychological, social and spiritual wellbeing of PLWHA. However,

of the PCC models identified in the studies retained, one study addressed only physical and psychological components of wellbeing [377]; two studies addressed social wellbeing in addition to physical and psychological wellbeing [375, 376]; and two studies addressed all 4 components of wellbeing [321]. Suggesting that less attention was paid to social wellbeing and more importantly spiritual wellbeing [155]. Notably, only one out of these five studies used validated tools to measure outcomes [320].

Exploration of contextual meaning and practice of PCC, development of more PCC interventions focusing on the specific contextual needs within the domains of physical, psychological, social and spiritual wellbeing of PLWHA; measuring these outcomes with validated tools; and additional examination of the feasibility and acceptability of such interventions were identified as potential future research direction.

The limitations of this review were the inclusion of only studies published in English resulting in publication bias and missing out on studies published in other languages. Furthermore, studies included had to say they were delivering PCC (albeit using a broad range of possible synonyms), implying that there is a possibility some studies may have delivered care in line with PCC but because they did not explicitly state that, those studies were excluded. Also, this review has a broad understanding of PCC which is Western in origin, and therefore findings cannot be generalised.

7.3.2 Thesis objective 2 (Qualitative interviews to inform intervention development)

Objective 2 aimed to explore the views of PLWHA and HCP regarding HIV care, what PCC means in the African (Ghanaian) context and what person-centred outcomes matter to PLWHA. Three interconnected themes emerged across PLWHA and HCP data: (i) care structures not built around the person, (ii) priority outcomes and components of PCC and (iii) re-engineering HIV care to be more person-centred. Many PLWHA and HCP participants reported symptoms and concerns in the domains of physical, psychological, social and spiritual wellbeing. This supports previous studies in the African context [102-104, 155], which found that PLWHA frequently experience distressing physical, psychological, social and spiritual symptoms and concerns, which negatively impact on their quality of life and influence their engagement and treatment adherence.

Both PLWHA and HCP held common and differing views on PCC which led to the development of a conceptual framework of PCC from the perspectives of stakeholders. Findings from this

qualitative study add to the previous evidence by revealing that the burden of person-centred symptoms and concerns is significant and impacts on every aspect of PLWHAs' lives. This research also showed pronounced sexual and intimate relationship concerns that required PCC. This may be because through interviewing PLWHA, the full impact of HIV on relationships and the family unit as a whole is revealed. Intriguingly, some of the HCPs had limited appreciation of the person-centred needs of PLWHA and the psychosocial effects on their wellbeing. This study provides novel insight into what constitutes PCC for PLWHA beyond the original western-oriented concept.

PLWHA understand PCC as care that involves them in their care decisions, which is concerned about the whole person and not only viral suppression and addresses what matters to them. PLWHA also view PCC as addressing broader social issues: living a normal life like anyone else, getting married and having children and being employed. In contrast, HCP described PCC as 'tailored care' and 'targeted care', however, this was focused on their own perspectives as to what is important, rather than that of the PLWHA. This was borne out in HCP data, which identified priority outcomes as biomedical (CD4, viral loads). This contrasts starkly with PLWHA data, which described social outcomes (living a normal life, getting married and having children). These differing priorities resulted in care that was not person-centred, as HCP expressed uncertainty about how PCC could be practiced, and a need for training.

A major challenge faced by PLWHA in low- and middle-income countries is the stigma associated with HIV disease, which also impact on service utilisation and physical health [397, 398]. It has been argued that PLWHA are caught in a sequence where psychological problems are compounded by stigma [399]. These and other issues relating to diversity, ethnicity, gender, sexual orientation, religion and socio-economic status could be addressed using a person-centred approach [162] in ensuring that patients have equal access to vital care service [400]. A recent study demonstrate the potential to increase PLWHAs' resistance to stigma using PCC delivery [382].

PCC is associated with improved clinical outcomes and cost effectiveness [401-403], as it allows services to target scarce resources at greatest need, which could also prevent further health service use due to unmet needs. 'Person-centred care made simple', a UK Health Foundation report presented evidence about cost savings and a decrease in healthcare services utilisation [404], which implies that when individuals are better informed, they could choose different treatments that are less expensive when supported to manage their own care more effectively

[405, 406]. Therefore, what is novel about this study that is different from other studies is that it explored the contextual meaning of PCC as applied to the symptoms and concerns of PLWHA in Ghana. This led to the development of a conceptual model and a framework to inform PCC delivery informed by the experiences and perspectives of PLWHA and their HCPs. This is clearly highly relevant to HIV care services in Africa.

7.3.3 Thesis objective 3 (Mapping qualitative data onto components of PCC theory)

Objective 3 aimed to map the qualitative data from objective 2 onto the components of the PCC theory adopted for this study, which is also the theory of change (ToC) to determine which components align with the theory and what additional components are required. The qualitative data aligned with the components of the PCC theory with the only overlap being the assessment and management of physical wellbeing, as the data reported care is primarily focused on physical wellbeing. The PCC described in HIV care within the West African context is one that should address broader aspects of wellbeing beyond physical needs including psychosocial and spiritual wellbeing. The existing approach to delivering HIV care in the community focused primarily on their physical wellbeing and did not involve them in decisions about their care. What stays the same is care focusing on physical wellbeing and what is different is care that will now address broader domains of need as described by PLWHA. Although these domains may be similar to the some of the models described in the Western context [152-154, 157, 159, 160], care addressing spiritual wellbeing seems absent except the one described by Mezzich [146].

However, HCP data revealed that the delivery of PCC could only be possible only if HCP were trained. This contrasts with a qualitative study conducted in South Africa which reported that HCP have a clear perceptions of PCC delivery however barriers such as resources, increased administrative work, HCP behaving unprofessionally hinder its implementation [407]. Making care more person-centred can lead to improvements in other areas of quality, particularly in safety and equity, leading to improved patient health status and satisfaction [408]. The past two decades have witnessed sizeable changes in health in sub-Saharan Africa and other low-income regions including the rapid rise of HIV/AIDS, to the encouraging declines in infectious diseases, and the growing burden of chronic diseases [409]. As health needs change and patient expectations rise, health systems in low-income countries will need to adopt a person-centred approach [410, 411] in order to improve health outcomes for patients. It has been argued that “all changes and new concepts that we initiate in order to make the healthcare sector more person-centred must include

all stakeholders. We must make sure that everybody is on board, or we are not likely to succeed" [412].

Implementing and achieving PCC delivery in healthcare systems requires relationship building between stakeholders through effective communication and acknowledgement of patients as experts in their own healthcare through partnerships that allow for sensitivity to patient's values, needs and preferences for care. Furthermore, there should be ongoing education and training for providers on PCC delivery, with a specific focus on holistic patient assessment, management of symptoms and concerns, collaborative care planning and delivery. Also, there should be increased understanding of patient's perspective for PCC to inform the content of PCC interventions and HCP training.

Traditionally, PCC has not been integrated into healthcare quality improvement [413]. Recent policies emphasise the value of patient views, which not only complement HCP perspectives, but also provide unique information about healthcare effectiveness [30, 414-418]. Despite many efforts to practice PCC, most health systems are challenged by effective implementation of PCC across the continuum of care therefore, shifting to PCC requires services and roles to be re-designed and re-structured to be more conducive to a PCC model [413]. Although the mapping of the qualitative data from thesis objective 2 resulted in the development of a framework to guide PCC implementation, there is still a need for health systems to be responsive to their specific contexts and to identify priority areas to encourage innovation for PCC. Policies and plans for strengthening health systems to better serve people with chronic conditions such as HIV/AIDS should be aligned with principles of PCC to strengthen patients' knowledge and skills to participate in and benefit from their care.

7.3.4 Thesis objective 4

Objective 4 integrated findings from objectives 1-3, modelling the potential processes, outcomes, and mechanisms of action for the intervention. This intervention was developed in an intervention development workshop held with an expert panel who have diverse experience and knowledge in developing PCC interventions in HIV population. The community-based enhanced care intervention (CECI) was developed with a training content for HCP training on PCC, communication, holistic assessment of symptoms and concerns, collaborative care planning and delivery with a twice weekly mentorship and supervision meetings with HCP on the CECI

intervention. The training content for the intervention was developed dwelling on palliative care resources for training on holistic care delivery in addition to those used in one of the studies identified in the systematic review [380]. The components of the CECI intervention focused on the qualitative data and the components of the PCC theory.

Appropriate outcomes and process measures for the CECI intervention were also chosen through information provided by the systematic review and qualitative study forming the 'modelling process and outcomes' step of the Development stage. The systematic review identified that there were symptom control and quality of life outcome measures that had previously been used in person-centred interventional study (TOPCare trial) [380]. This study used validated measures to measure person-centred outcomes in PLWHA, which included the APCA POS and MOS-HIV. These outcome measures identified from the systematic review were selected and used in the feasibility cluster trial evaluation of the CECI intervention, in addition to an additional person-centred outcome measure (Positive Outcomes), which is an HIV-related outcome measure based on Lowther et al.'s [380] recommendation. Process measures were also selected based on issues related care processes as discussed in the qualitative data. The person-centred process measures chosen were the CARE Measure and Picker Patient Experience Questionnaire. These process and outcome measures appeared to be the appropriate measures as the qualitative study in objective 2, identified that PLWHA had holistic and PCC needs which did not just focus on symptom control or quality of life but included every aspect of PLWHAs' life.

7.3.5 Thesis objective 5

Objectives 5 formed the Feasibility stage of the MRC guidance, which focussed on testing the CECI intervention in a parallel phase II mixed methods feasibility cluster randomised controlled trial (cRCT). The cRCT was conducted in two community clinics (randomised as intervention and control) and provided preliminary information related to the CECI intervention components and outcome measures chosen in objective 4. A total of 60 participants (30 participants per cluster) were recruited into the feasibility cRCT and HCP in the intervention in the intervention arm were trained on CECI delivery prior to the commencement of the first session of the intervention delivery to PLWHA. The quantitative results showed a positive and significant potential effect on all outcome and process measure scores from Timepoint 1 to final Timepoint 3. This suggests that the CECI intervention may improve the person-centred outcomes for PLWHA in a clinically meaningful way. At the implementation of CECI intervention, evidence based guidelines were

used and a holistic symptoms and concerns assessment in the domains of physical, psychological, social and spiritual wellbeing, collaborative care planning and care delivery based on care plan agreements to meet care goals set were carried out. Ongoing management of PLWHAs' holistic care needs were carried out by the HCP trained to deliver the CECI intervention at the community clinic.

It is possible that the delivery of the CECI intervention using these evidence based guidelines, the twice weekly supervision meetings and the ongoing management of the holistic care needs identified during holistic symptom and concerns assessment resulted in the improvements in the scores seen in all the outcome and process measures used. It is difficult to know whether the benefit from the CECI intervention seen is due to the PCC delivery or the added time that HCPs spent in assessing and planning care together with PLWHA. However, the results are promising and warrant further investigation. Of note HCPs who provided the CECI intervention in the community setting also reported the positive effect and the difference the CECI intervention made on them as well as PLWHA. The actual process of the CECI delivery, having a clear individualised care plan and PLWHA being supported by HCPs to contribute to their care may have helped in the increased PLWHAs' process measure scores seen in the quantitative results.

A post-trial qualitative interview conducted with a purposeful sample (n=20 PLWHA and n=7 HCP) from participants who took part in the feasibility cRCT, revealed a general acceptability of the CECI intervention across PLWHA and HCP data. The quantitative and qualitative data collected during this feasibility cRCT proved the CECI intervention to be both feasible and acceptable. At the CECI delivery, not all PLWHA wanted to get involved in care planning decisions as they were not sure if it was their responsibility to do so. This finding indicates a need to train PLWHA on how to contribute to their care decisions in a future definitive trial. For some PLWHA, the CECI delivery gave them the opportunity to have important conversations with HCP. However, many PLWHA who had not wanted to discuss or get involved in their care decisions and to plan their care later went on to have subsequent discussions with their HCPs in the weeks after the first CECI appointment. This in itself is an important influence of the CECI intervention.

Feasibility criteria set for this cRCT were to recruit 60 participants across the two cluster sites within 8 weeks, to retain 80% of the sample after 3 months follow-up (final timepoint) and to determine CECI acceptability by both HCP and PLWHA. All these criteria were met. This was largely due to the successful delivery of the CECI intervention by HCP and making time to attend the twice weekly supervision meetings. The study design of a feasibility cRCT also seemed to

have worked well. All PLWHA participants interviewed were very grateful to have received the CECI intervention. Both PLWHA and HCPs praised the CECI intervention particularly its holistic approach to assessment of symptoms and concerns and the involvement of PLWHA in their care decisions. This is the first time a complex intervention looking at improving the person-centred outcomes for PLWHA has been developed using the MRC guidance. Compared to the TOPCare trial [320], which trained only a member of staff to deliver the PCC intervention, this study focused training on the multi-professional team which has greater potential system change and coverage.

7.4 Methodological considerations

7.4.1 Feasibility studies

Feasibility studies are pieces of research done before a main study in order to answer the question “Can this study be done?” [419]. The primary outcome for this feasibility cRCT is recruitment and retention. Among some the uncertainties addressed by this feasibility cRCT in order to improve their precision for a successful definitive trial include (i) recruitment (willingness of clinicians to recruit; number of eligible participants; consent process; and willingness to participate); (ii) intervention (willingness of the two clinics to be randomised; acceptability of the intervention, impact of the intervention, and acceptability of process measures); and (iii) outcome (characteristics of the proposed outcome measure, follow-up rates, response rates to questionnaires and adherence, time needed to collect and analyse data, and selection of right outcome measure [419, 420]. In order to reduce research waste, theoretically informed interventions developed are required to undergo feasibility testing [319].

7.4.2 Cluster randomised controlled trials

Cluster RCT involves the allocation of groups of subjects (PLWHA) to different treatments [355, 356]. This thesis used a cluster RCT rather than individual randomisation in order to reduce/ minimise treatment ‘contamination’ [357] between the intervention and control arms. Cluster RCT is preferred because, while an individual RCT may be better suited to determining whether a novel therapy works in patients with a given disease or condition, a cluster RCT is better able to evaluate whether a new standard of care, guideline recommendation, or other community-wide, practice-wide, hospital-wide, or system-wide change is affecting patient outcomes [421]. Therefore, the strength of using the cluster RCT has been that a team of HCP have been trained to deliver this

novel person-centred intervention which may translate into practice-wide change as well as change in health systems.

7.4.3 Recruitment and retention

A recruitment rate of 78% (n=39) and 87% (n=60) was achieved in Phase 2 and 3 respectively. The feasibility criteria set estimated a retention rate of 80% however at the final follow-up timepoint (3-months post intervention) retention was 97%. PLWHA demonstrated good participation in the CECI intervention which could be attributed to the person-centred and holistic approach used in delivering care in addition to PLWHA involvement in their care decisions and delivery as this was a novel experience for them. While this study did not provide any incentive for participation in the study, participants transportation fares (which was estimated using the longest distance travelled by participants to the study sites) were reimbursement. The post-trial interview data did not make any reference to this transportation reimbursement as influencing any outcome of care. However, the TOPCare trial [380] offered participants a flat rate regardless of the distance travelled. Although this is a recommendation by national research council [422], it has also been criticised in terms of it being mostly excessive, unaffordable for studies not funded by a research grant, inappropriate and most importantly unfair to participants who may incur additional cost as a result of travelling longer distances [423].

The TOPCare trial offered participants almost the equivalent of a day and a half's wages to reimburse their transport costs which impacted on the therapeutic effect of their intervention [380]. This appears excessive, although recommended by the local stakeholders and was ethically approved by ethics committees. Trial communities generally recognise that giving study participants money for transport reimbursement is a transfer of net value to the study participant [424, 425], which usually occurs in contexts where participants of the research are extremely poor [422] compared to the research institution. A study conducted to support the development of guidelines for benefits and payments for research participants, revealed that although it is usually agreed that participants should be compensated for expenses, excessive payments distort the decision making processes, as individuals in poverty could participate against their better judgement [422]. The author therefore recommends that such payments be set based on distance between study sites and residential zone, in addition to a small amount for a drink or snack [422]. Whilst this approach, introduces a layer of complexity to transport reimbursements, it would lessen the therapeutic effect of this extra money and explain the actual effect of the intervention.

As participants in the study conducted by Lowther et al. described their ability to purchase certain items that they could not afford previously, resulting in the researchers' difficulty in attributing the causal mechanism of the relief described by participants [380]. Therefore, a future definitive trial should consider the specific distance travelled by participants to the study site in order that such final reimbursements does not influence participants' treatment outcomes.

7.4.4 Intervention delivery and outcome

The constraint of the PhD timeline meant that the intervention was delivered over a maximum of three months. A future trial may offer more flexibility in the length of time between each intervention session. The process of randomisation was successful as a result of the willingness of the two clinics to be randomised. The intervention was acceptable to both PLWHA and HCP, although HCP expressed that the intervention required longer time to deliver that the usual time spent on patients. Participants did not seem to have any issues with the process and outcome measures used, apart from few expressions of duplication of information/ outcomes being assessed by the measures. Refinement of the logic model and intervention content during dissemination of the thesis findings can facilitate delivery of an improved intervention.

The follow-up rates, response rates to the measures and adherence were good however, uncertainties still remain relating to outcomes. Methods to improve the process evaluation should be developed taking into consideration the context of each study site, as this will enhance the interpretation of the role of mediators on study findings. This should include improved evaluation of intervention fidelity (intervention design, training of providers, intervention delivery, receipt of intervention, enactment of skills gained from the intervention), which could involve production of a feasibility protocol [389, 426].

7.4.5 Incidental benefits derived from completing measures

Participating in this feasibility cRCT and responding to the questions in the outcome measures was meant to be just a data collection exercise. However, in a socially isolated and stigmatised population such as PLWHA, interacting with a friendly, non-judgemental and accepting researcher had therapeutic effect. As demonstrated in the findings from the post-trial qualitative data for participants in the control arm, it was reported that the thought of meeting the researcher each time they visited the study site to respond to questions in the measures used motivated participants to attend their appointments.

7.5 Communication in healthcare

One of the benefits of the CECI intervention as discussed by participants is the importance of openness in communication with HCP and researcher. They spoke of being able to express themselves with regards to what matters to them and being interacted with in a way which encouraged them to respond in an equally free and open manner. It is likely that the researcher emphasised the importance of talking freely for data collection. It is essential that the interviewee understands that information that they might wish to convey is acceptable and interesting to the researcher, who works to create an atmosphere of openness and acceptance where interviewees do not fear judgement when disclosing their personal, intimate experiences [427]. To reduce interviewer bias, researchers in qualitative research are advised to sustain "empathic neutrality whereby the researcher uses personal insight while taking a non-judgemental stance" [427]. To PLWHA, it is possible that this message could be read as, 'my experience is acceptable and therefore I am acceptable'. This way, the research process contributes to the feelings of increased self-worth and acceptance reported in the qualitative data.

Effective and sensitive communication could have implications for PCC; due to both the way in which information was given and the benefit of the information itself. Participants in this study described the positive effects of being listened to and sharing their burdens with the researcher on their person-centred needs and wellbeing. The work of Payne et al, exploring communication and in primary care, found a positive approach such as that demonstrated by the study team, was associated with patient satisfaction [428]. Similarly, in a recent systematic review, high quality communication between physician and patient was found to positively influence emotional health, resolve symptoms, improve function and pain control [152]. When functionally and subjectively measured, skilful quality patient physician interaction which increases patient control and includes positive affect and health information has been found to be associated with better health status [429].

Findings from the thesis Phase 2 qualitative interviews evidence that participants felt unsafe to discuss their problems amongst their community. Similar findings have been reported from a study of PLWHA in South Africa, which identified the need for a safe forum where PLWHA could exchange information about how they could apply health information to their lives, within the context of a stigmatising condition [430]. Participating in this study provided similar space and opportunity to reflect on the experience of living with HIV. Campbell et al. suggest that reflection

and review, create the beginnings of critical thinking and facilitate the shift from victim to empowered actor, and help PLWHA to develop the confidence to engage with and positively influence their environment [430, 431]. Therefore the training HCP received on communication as part of the CECI intervention enabled them to demonstrate high quality communication skills which enabled participants to express themselves freely, which was therapeutic in itself, but also created a therapeutic relationship, in a similar way to unconditional positive regard, and positively influenced the delivery of PCC to PLWHA.

7.6 Strength and limitations

The success of this study is a major strength including achievement of recruitment and retention targets, response rates in addition to the acceptability of the intervention which was developed specifically for HIV population. The sampling frame was achieved, and the three Phases of the thesis were conducted within the planned time frame, with a robust randomisation process for the feasibility trial which also achieved the a priori feasibility criteria. The trial was registered and was reported according to CONSORT extensions for pilot and feasibility trials.

A maximum variation sample was achieved for the qualitative study, and the study oversampled MSM (29%) in thesis objective 2, which is notable considering that same sex relationships are not legalised in Ghana. However, during the time period the researcher was unable to recruit heterosexual participants between the age group 20–29 years for the development interviews; hence, their specific views and experiences may not have been represented. Furthermore, it is possible that some subtleties derived from the data interpretations may have been lost due to translated transcripts from Twi to English, as there is not always a direct translation from Twi to English. In order to mitigate against this, at the end of each interview the researcher summarised what was discussed during the course of the interview to confirm with the interviewee whether that was the view they put across and if possible, provide further clarification. Also, the researcher sent the translated transcripts together with the corresponding audio recordings to an official Twi-English translator to verify the transcriptions.

The feasibility cRCT only recruited from two community clinics of which only one clinic received CECI to improve person-centred outcomes for PLWHA. Therefore, findings do not represent the wider PLWHA population. Also, the researcher was involved in all study stages including study design, implementation and subsequent analysis of data for which it was difficult for the

researcher to be blinded. As a result, this may have introduced bias specifically in the assessment of all participants at both study sites, the feasibility and acceptability of CECI training and delivery, and the analysis of study data. However, the strength of this study is the fact that CECI training and delivery were conducted at the cluster level where a whole team of HCP were trained to deliver the CECI. Therefore, the delivery of CECI is neither dependent on a single staff member who may be on sick leave nor the intervention is about their specific skill alone that may not be transferable. It is about change in culture and practice not an individual's performance.

Moreover, the same researcher recruited participants (PLWHA and HCP) from the sample that participated in the feasibility cRCT for the post-trial interviews, as well as carried out the interviews. Given the researcher's relationship with the study participants may not have felt comfortable to share negative comments about the CECI intervention or the study. Also, due to cost and time limitation, a pre-determined set number of interviews (n=20 PLWHA and n=7 HCP) were carried out. It is possible that there were further views and experiences that may have emerged if further interviews had been carried out. In a future definitive trial, the researcher would sample and interview PLWHA and HCP with the intention of reaching thematic saturation. The CECI intervention is a complex intervention with several different active components. As a result, there will have been some variation in the care received by each PLWHA.

As discussed, efforts were made to standardise CECI delivery as much as possible including training of HCP, use of holistic assessment tools and care plans, twice weekly supervision meeting on CECI delivery and to address other issues that may have arose during the intervention delivery. This level of standardisation does seem reasonable considering the time and cost limitations. However, in a further evaluation trial of CECI intervention, it would be important to ensure further standardisation of the components delivered by including a component on PLWHA training to empower them to engage and contribute meaningfully towards planning and making decisions about their care.

On reflection, the CECI intervention delivery session could have been digitally recorded to further assess fidelity with subsequent training to promote consistency. In addition, this would allow detailed information gathering on the content of the CECI intervention, which may provide insight on the mechanisms of action of the CECI intervention and allowed deeper consideration and understanding of which part of the complex intervention is effective. Recording this information is unlikely to have been too burdensome in terms of cost or time and would have been helpful in

considering the real-life implications of delivering the CECI intervention in both hospital and community settings of HIV care within the Ghana Health Service.

The Feasibility cRCT was carried out at only two community clinics in Ghana therefore generalisability nationally and internationally may be limited and warrants further investigation. Within the constraints of cost and time, it was not possible to include more cluster sites to the cRCT. However, any future evaluation trial would ideally need to include more cluster sites, nationally and if possible, internationally within African context to assess outcomes across different cultures and to ensure generalisability of findings.

Furthermore, the same researcher conducted the HCP training on the CECI intervention, facilitated the twice weekly supervision meetings with HCP as well as evaluated the training session after training. This is a source of bias as the HCP professionals may want to be loyal to the trainer and therefore give good feedback on the training. In a future evaluation trial, the facilitator of the CECI intervention training should be different from the person who evaluate the training. As this was feasibility cRCT, it was not powered to show effectiveness. Therefore, any positive results should be interpreted with caution and must be evaluated in an adequately powered trial. This may also have potentially diluted the effect size of the intervention.

7.7 Implication for practice, policy and research

7.7.1 Implication for clinical practice

There is increasing advocacy for holistic and person-centred care delivery for PLWHA in order to achieve global treatment targets [48]. The CECI intervention supports the holistic and person-centred approach to care delivery for PLWHA. This study has shown that symptom and concerns of PLWHA may be improved with routine use of a holistic assessment tool in assessing the needs of patients. As both PLWHA and HCP acknowledged that psychological, social and spiritual needs are under-assessed and therefore, inadequately managed. This perhaps indicates a routine neglect of psychosocial and spiritual care in standard HIV management, but also a lack of training and confidence to manage these issues. In conjunction with the RN4CAST data [432], this is a demonstration of a pattern of inadequate provision of psychosocial care across international settings. The evidence hints that a lack of time to interact with patients may be an important limitation [433]. It has been argued that when time is constrained, nurses prioritise medical tasks to process patients through the system for medical discharge [433], this is most clearly observed

when staffing levels are low [434]. As the standard HIV management clinic is extremely busy (30 to 40 patients per day, see Table 4), it is expected that the neglect of psychosocial and spiritual care is as a result of increased workload and subsequent time constraints.

This neglect of psychosocial and spiritual care can be further attributed to the lack of importance placed on person-centred care or holistic wellbeing by HCP working in standard HIV management clinics. Evidence from the UK revealed that when patients in primary care presented with unexplained physical symptoms and suggested potential psychosocial causes, GPs were more likely to suggest physical investigations and interact with a low level of empathy [435]. These findings imply that even when patients present with physical symptoms recognised as expressions of unmet psychosocial need, they are not managed appropriately or referred to appropriate care, even in a well-resourced healthcare setting of a UK GP practice. As mentioned in the background chapter 1 (section **1.3.4.3**) of this thesis, nurses trained in Ghana receive a comprehensive training on human anatomy and physiology, pharmacology, nutrition and dietetics, community, psychiatric, paediatrics, obstetrics, medical and surgical nursing, in addition to psychology among others [98]. While the course is comprehensive in terms of the specialities covered, it appears to neglect communication skills, person-centred care and the importance of managing the holistic needs of patients, focusing instead on diagnosis and management of disease. This focus on medical management in nurse training does not seem to prepare nurses to care holistically for their patients. The lack of emphasis on PCC in medical education remains a barrier to its implementation [436], resulting in gaps in practice. Evidence for the effectiveness of psychosocial support in the management of physical outcomes in chronic conditions is established and psychosocial support is now mandated as part of supportive cancer and coronary care [437-439]. The findings of this study indicate that psychosocial needs are disappointingly under assessed and poorly addressed in HIV care.

Strategies for improving HIV care should include relationship building among stakeholders (PLWHA and HCP) through effective communication and acknowledgement of PLWHA as experts in their own healthcare through partnerships that allow for sensitivity to patient's values, needs and preferences for care. There should be ongoing education and training for providers on PCC delivery, with a specific focus on holistic patient assessment, management of symptoms and concerns, collaborative care planning and delivery. Increased understanding of patient's perspective for PCC should inform the content of HCP training.

PLWHA should have access to specific social support networks as a forum to discuss their experience of HIV in a non-judgemental environment, free from the effects of stigma. Findings from the qualitative development interviews indicate the importance of social and emotional support and the potential to learn from others in the same situation. The stigmatising nature of HIV means that a safe and non-judgemental forum to discuss their experiences is rarely available, and evidence suggests that this could benefit patients in terms of health education and social and emotional support [430]. HCP should be supported by their clinic management to develop a more person-centred, holistic, respectful, caring and non-judgemental approach to care. This may involve continuous professional development through training, increasing HCP numbers to reduce workload, stress and burnout, role modelling person-centred approach to HIV care and improving teamwork in clinics. Clinical supervision or peer debriefing would also recognise and mitigate any negative effects of the emotional labour of this approach to nursing. This would increase HCP and PLWHA quality of life and well-being.

7.7.2 Implication for policy

Findings from this study provide evidence that should be integrated into HIV care guidelines, for the promotion of person-centred care for PLWHA. Policies and plans for strengthening health systems to better serve people with chronic conditions such as HIV/AIDS should be aligned with principles of person-centred care. Also, multidimensional needs of PLWHA should be holistically assessed at regular intervals. This, with appropriate management and referrals, will reduce the distressing physical, psychological, social and spiritual symptoms and concerns experienced by PLWHA which also impact on treatment adherence, wellbeing and quality of life [5, 102][430].

Furthermore, more material support should be made available, consisting more than just financial reimbursement, and be more responsive to the local context and need. This would mitigate the additional constraints placed upon families with members living with HIV/AIDS, especially if the affected member is the breadwinner and not could contribute towards the extra costs incurred through illness, such as CD4 and viral loads tests not covered by basic clinic care; this would also relieve psychological distress. Income generating avenues should be explored for this patient population, so as to lessen the effects of sickness due to HIV on family life. This may involve collaborations with community-based organisations in the area, including working in areas such

as microfinance, mobile money operators, soft loans for petty trading or projects that increase skills and employment options for PLWHA.

7.7.3 Future direction of research in this area

Given that this feasibility cluster trial is both feasible and acceptable, in addition to meeting a priori feasibility criteria, there is a need for a definitive trial of this intervention, this is also the researcher's next plans for postdoctoral research. The main research question for this definitive trial would be does the CECI intervention work?

The post-trial interview data revealed that although the holistic assessment tool was able to capture more symptoms and concerns, it also lengthened the time allocated for clinical reviews as it took HCP at least 30 minutes to see one patient, and at most 60 minutes to see others, coupled with the completion of care plans. Therefore, a future definitive cluster trial, should carefully consider the cost implications of delivering this intervention. As this was a feasibility trial, it is not in the scope of feasibility trials to do a full cost analysis. Therefore, the researcher proposes a full health economic/costing component to be added to a future definitive trial to understand costs and savings on this intervention, as well as investigate the actual time spent on delivering the intervention. However, the researcher hypothesises that the CECI intervention is potentially cost saving due to prevention of problems and health service use, reducing admission and crisis management and retention in care.

Further research is also needed to determine and understand the active ingredients of CECI by closely examining the process of CECI delivery. Aspects of CECI delivery which need to be considered should include content of each CECI component including the holistic assessment, collaborative care planning and delivery and how HCP involved PLWHA in making their care decision. This may be done through quantitative or qualitative measures. Further studies/ next intervention should target both HCP and patients' outcomes to also evaluate both HCP and patients' outcomes across different cluster sites. This may provide valuable information on how the CECI intervention works in community settings for PLWHA. In planning a definitive trial, a decision on a primary outcome measure is crucial as this feasibility could not specify what primary outcome measure could be used. The results of the definitive trial could be used to inform change in clinical practice which might lead to a future policy on PCC delivery in HIV clinical care at the national level. Additionally, more empirical studies are required to evaluate the suitability of

introducing the CECI intervention not only to HIV population but also to other disease groups within the West African region.

This emphasis on theoretically driven intervention development prior to testing in a feasibility trial contributes to reducing research waste in person-centred care research [319]. The methods and findings are currently undergoing peer review for publication, this will permit refinement prior to efficacy testing. However, this is a complex intervention delivered in complex system therefore knowledge gaps relating to contextual mediators and health economics at the level of the health care system and participants remain [440].

7.8 Personal learning and reflection

Undertaking this PhD has given me access to a patient group with whom I had limited prior experience. Through the experience of interacting with PLWHA, I have developed a more in depth understanding of the symptom burden they experience and the essential support they require to mitigate these symptoms. During data collection and the qualitative interviews, it became clear that for many of these patients, living with HIV is complex condition by which they feel overwhelmed. Undertaking this study has demonstrated to me the importance of providing person-centred and holistic support to PLWHA as they cope with an unpredictable condition which affects every aspect of their lives. My greatest achievement conducting research in HIV population has also been that I was successful in recruiting about 29% of MSM who contributed their care experiences and challenges being homosexuals. This is notable considering that same sex relationships are not legalised in Ghana and those who practice same sex relationships are at risk of disclosing their sexual orientation. Most importantly this has contributed to the data on how to improve care services to be more person-centred towards MSM in Ghana.

As this feasibility cRCT collected data over 3 months, I had a number of interactions with each PLWHA. This experience has informed my clinical practice in a positive way as it has given me a much greater understanding of the burden which a chronic condition like HIV presents. The training received and the experience of undertaking the qualitative interviews, have helped me to further develop my clinical skills. This experience has enabled me to be better equipped to explore PLWHA illness experience with them. This PhD has made me deeply aware of the far-reaching impact of having unmet person-centred needs and how this impacts every aspect of PLWHAs' lives. Throughout this PhD I have been touched by how PLWHA struggled in silence because they did not have the opportunity to share what mattered to them. They were unaware there could be an intervention that could assess and manage their needs holistically and suffered without complaint. During data collection and the post-trial qualitative interviews, it became clear that PLWHA were incredibly grateful for their involvement in their care and all the support they received as a result of the CECI intervention. This has made me aware that care services intended for PLWHA need to be directed at their holistic needs (physical, psychological, social and spiritual).

Lessons were learnt throughout the process of completing this PhD. The first lesson relates to gaining access to study sites and participants, which required the researcher to build good rapport with the clinic leads and HCP in respective clinics including helping to screen patients at the clinic. The clinic leads were also offered authorship of any publications that resulted from this PhD, which led to significant cooperation from the clinic leads of the two study sites. This cooperation also led to the successful negotiation with both study sites to schedule a monthly appointment for all participants during the intervention delivery in order to have an even time for outcome assessment for both the intervention and control arms. Secondly, the researcher had to transition from being a nurse to a qualitative researcher by acknowledging that while the researcher has clinical skills or experience that are related to the subject of enquiry, those experiences and skills could not be applied in the research interview in the same way as the insight sought would be used clinically. This reality reflected the researchers' underlying shift from being someone whose expertise were being sought (nurse), to someone who was an inquirer (the researcher) seeking out the experience of PLWHA in order to better understand their experiences, symptoms and concerns. The researcher worked hard, with support from her supervisors, to manage this transition from clinician to qualitative researcher. Achieving this balance helped the researcher to identify the actual care needs of PLWHA to inform the development of a theory-driven and culturally appropriate person-centred intervention that could best address their needs. Thirdly, the full cooperation of HCP during interviews, the intervention training, mentorship and supervision was secured by the provision of daily refreshments for all HCP during and at the end of the study. Additionally, training certificates were awarded to all HCP who participated in the intervention training which some of the HCP were heard to say with pride "I have a training certificate from King's College London". Finally, closing and withdrawing from the study sites was quite difficult to manage, particularly at the control arm, where the continued presence of the researcher during the outcome data collection throughout the study was perceived by participants as an intervention itself. On reflection, experiencing the disappointment of these participants and not knowing how this disappointment would impact on their care as the researcher withdrew from the sites was disturbing. However, all participants were warned ahead before the final outcome data was collected that the study was coming to an end.

I believe that governments and ministries of health have a duty to ensure that groups such as PLWHA receive an equitable share of national resources to foster the development of

interventions that address their holistic needs. I would hope that this PhD helps to highlight some of these issues and may facilitate development of person-centred interventions going forward. Although this PhD has been hard work and emotionally draining at times, I have experienced a great deal of personal enjoyment from the sustained contact over time with PLWHA and their HCP. I felt a genuine pleasure in learning of the disease experiences of PLWHA including feeling very privileged that participants felt able to open up and shared their intensely personal issues. It is my believe that this PhD has positively influenced my clinical practice through not only making me a better listener, as a result of skills acquired during qualitative interviewing, but also more considerate of PLWHA and the far reaching and devastating impact of HIV/AIDS on their lives.

This PhD has also improved my academic and research skills as I learned from colleagues how to quickly adapt to good study habits, recording and annotating reading relevant to my thesis, writing regularly and attending relevant courses. It was difficult for me to discriminate between concepts or constructs requiring deeper understanding for my thesis, and those that were just interesting. My supervisors and the Thesis Progression Committee helped me to develop convergence, focus and research management skills. I learned to prioritise, to ensure that my learning, developing research skills and research activities were directed towards answering my thesis aim and objectives. I have developed pragmatic and organisational skills during management of two study sites and a feasibility trial, and my academic skills have developed during data analysis and academic writing. I have understood that the quality and usefulness of research is dependent on asking important, relevant questions, choosing the appropriate methods to answer them and acquiring the resources needed to do it. The research skills gained at each phase of the thesis have helped me prepare for a career in research.

7.9 Conclusion

This study followed the Medical Research Council Guidelines and used sequential mixed methods design to develop and test the feasibility of delivering a person-centred theory informed community-based enhanced care intervention for PLWHA. This study has shown that it is possible to deliver person-centred intervention for PLWHA, and to recruit and retain participants into a cRCT. Findings also suggest that a person-centred model of care for PLWHA may improve their clinical and person-centred outcomes. Further research is needed to implement the learning gained from this feasibility cRCT and to evaluate these potential effects in a larger evaluation trial. This feasibility study provides a major contribution towards the understanding of the feasibility and acceptability of this person-centred intervention (CECI). It also provides valuable insights into the potential mechanism of action of the CECI intervention in PLWHA, in addition to the potential challenges associated with undertaking research in this population. Recruitment was successful with no significant challenges and the total sample (n=60) for the feasibility testing were recruited within 6 weeks of starting recruitment. Retention rate of recruited participants was also good (97%), particularly in the context of multiple follow-up assessments.

This is the first study to develop and test the feasibility of a person-centred intervention for PLWHA in Ghana and possibly one of the few globally. Intervention adherence and PLWHA compliance with the intervention were excellent with minimal missing data. These findings demonstrate that the CECI intervention could be appropriate for use in HIV population. The study also demonstrated that a cluster RCT design is feasible and acceptable to be undertaken with PLWHA having met the recruitment and retention targets including our a priori feasibility criteria. These findings add to the evidence base and support further development and evaluation of these types of interventions, which this study demonstrates are feasible with potential effect sizes and justify a future definitive trial of CECI.

Uncertainties relating to the development and feasibility of the person-centred intervention were explored during the development stage including data contributed by PLWHA and HCP to inform the selection of intervention components and corresponding outcome and process measures; mapping this onto the training content for HCP and the feasibility trial process. Integration of theory (theory of change) and evidence resulted in a person-centred intervention to optimise the

skills of HCP to assess and manage the symptoms and concerns of PLWHA holistically. A conceptual model of person-centred care informed by the perspectives of PLWHA and HCP in community HIV management in Ghana, a framework for person-centred care delivery informed by the WHO's framework on integrated people-centred health services and a logic model were produced for a cluster randomised controlled feasibility trial. This feasibility trial revealed that it is feasible to recruit and retain PLWHA diagnosed for at least six months in a trial of a community-based enhanced care intervention. Participant satisfaction with trial procedures and the intervention, and intervention fidelity were high.

These findings have implications for clinical practice, research and policy. This thesis presents a person-centred model of community-based enhance care intervention that can be integrated within existing community HIV management services. This may improve outcomes for PLWHA including wellbeing and quality of life. A definitive trial to examine the effectiveness of the community-based enhanced care intervention is feasible. However, efforts should be made to train PLWHA to strengthen their knowledge and skills to participate in and benefit from their care; increase the duration of training for HCP and allow more time for practical demonstrations using role plays, and to examine the effects of this intervention over longer periods than studied in this thesis.

This thesis has contributed to science in relation to understanding the contextual meaning and practice of PCC for PLWHA in Sub-Saharan Africa, which has informed the development of a culturally appropriate person-centred intervention for PLWHA. If proven to be effective and cost saving, this intervention may be applicable in HIV population within Africa.

Prior to starting this PhD, it was clear that person-centred care is a Western concept that was used to underpin this thesis. However, this study demonstrates that the Western conceptualisation does not directly align to the cultural context of Ghana. This is because person-centred care has been interpreted and applied differently in different contexts [39]. Also, in the context of Africa, it has been argued that the wishes of the patient are often a reflection of the wishes of their families [39], implying that the care is less individualised and more family-centred. Although this assertion may be true, it does not seem to apply to the context of HIV care due to the highly stigmatised nature of the disease leading to potential non-disclosure or disclosure resulting in loss of family and social support. Consequently, person-centred care for people living with HIV/AIDS in Ghana means individualised care that is focused on addressing specific social needs such as poverty (although there is not a charge to access healthcare, people regularly

incur travel and other costs in order to attend services), relationship support (being able to marry whoever they want irrespective of their HIV status); information needs (such as knowing what treatment options are available to them in addition to information on when to have unprotected sex for discordant couples); being given the opportunity to contribute to their care decisions; and in the case of MSM, being able to access any public health services without any fear of dual discrimination (being discriminated against for their sexual orientation and being HIV positive).

The findings of this study represent a novel contribution to the evidence base for the development and evaluation of a person-centred model of care, which could help in meeting the multidimensional needs of PLWHA experiencing HIV infection as a chronic condition, particularly within the constraints of healthcare systems in LMIC.

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Appendix A. KCL ethics approval for study Phase 2

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KING'S College LONDON

Mary Abboah-Offei

27 June 2017

Dear Mary

LRS-16/17-4507

I am pleased to inform you that full approval for your project has been granted by the BDM Research Ethics Panel

- Ethical approval is granted for a period of **three years** from 27 June 2017 You will not receive a reminder that your approval is about to lapse. It is your responsibility to apply for an extension prior to the project lapsing.
- You should report any untoward events or unforeseen ethical problems to the panel Chair, via the Research Ethics Office, within a week of occurrence. Information about the panel may be accessed at: http://www.kcl.ac.uk/innovation/research/support/ethics/committees/sshl/reps/index.aspx
- If you wish to change your project or request an extension of approval, please complete and submit a Modification Request to crec-lowrisk@kcl.ac.uk. Please quote your ethics reference number, found at the top of this letter, in all correspondence with the Research Ethics Office. Details of how to complete a modification request can be found at: http://www.kcl.ac.uk/innovation/research/support/ethics/applications/modifications.aspx
- All research should be conducted in accordance with the King's College London *Guidelines on Good Practice in Academic Research* available at: http://www.kcl.ac.uk/college/policyzone/assets/files/research/good%20practice%20Sept%2009%20FINAL.pdf

Please note that we may, for auditing purposes, contact you to ascertain the status of your research.

We wish you every success with your research.

Best wishes,

Ms Laura Stackpoole

Senior Research Ethics Officer

For and on behalf of:
BDM Research Ethics Panel

Final Dual Review Decision: Full Approval

Advice and Comments (do not have to be adhered to, but may help to improve the research)

H? - Will your trained male and Muslim researcher/research assistant require remuneration for this role? Will their training involve appropriate ethical and other content so as to assure the rigor and integrity of your study.

Appendix B. GHS ethics approval for study Phase 2

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Tel: +233-302-681109
Fax + 233-302-685424
Email: ghserc@gmail.com

MyRef. GHS/RDD/ERC/Admin/App/684
Your Ref. No.

Mary Afi Dela Abboah-Offei
King's College London
Department of Palliative Care, Policy and Rehabilitation
UK

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC: 16/06/17**
Project Title	Development and Testing of a Novel Community-based Intervention of Integrated Palliative Care to Improve Person-centred Outcomes for People Living with HIV/AIDS in Ghana
Approval Date	18th July, 2017
Expiry Date	17th July, 2018
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report **after completion** of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....
DR. CYNTHIA BANNERMAN
(GHS-ERC CHAIRPERSON)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra

Appendix C. NOGUCHI ethics approval for study Phase 2

NOGUCHI MEMORIAL INSTITUTE FOR MEDICAL RESEARCH
Established 1979
A Constituent of the College of Health Sciences
University of Ghana

INSTITUTIONAL REVIEW BOARD

Phone: +233-302-916438 (Direct)
+233-289-522574
Fax: +233-302-502182/513202
E-mail: nirb@noguchi.ug.edu.gh
Telex No: 2556 UGL GH

Post Office Box LG 581
Legon, Accra
Ghana

My Ref. No: DF.22
Your Ref. No:

6th September, 2017

ETHICAL CLEARANCE

FEDERALWIDE ASSURANCE FWA 00001824 **IRB 00001276**

NMIMR-IRB CPN 004/17-18 **IORG 0000908**

On 6th September, 2017, the Noguchi Memorial Institute for Medical Research (NMIMR) Institutional Review Board (IRB) at a full board meeting conducted continuing review and amended your protocol titled:

TITLE OF PROTOCOL : **Development and feasibility testing of a novel community-based intervention of integrated palliative care to improve person-centred outcomes for people living with HIV/AIDS**

PRINCIPAL INVESTIGATOR : **Mary Abboah-Offei, Ph.D. Cand.**

Please note that a final review report must be submitted to the Board at the completion of the study. Your research records may be audited at any time during or after the implementation.

Any modification of this research project must be submitted to the IRB for review and approval prior to implementation.

Please report all serious adverse events related to this study to NMIMR-IRB within seven days verbally and fourteen days in writing.

This certificate is valid till 5th September, 2018. You are to submit annual reports for continuing review.

Signature of Chair: .....
Mrs Chris Dadzie
(NMIMR – IRB, Chair)

Appendix D. KCL ethics approval for study Phase 3

Research Ethics
Office

Franklin Wilkins Building
5.9 Waterloo Bridge Wing
Waterloo Road
London SE1 9NH
Telephone 020 7848 4020/4070/4077
rec@kcl.ac.uk

KING'S College LONDON

Mary Abboah-Offei

2 July 2018

Dear Mary,

Study Title: Phase II mixed methods feasibility cluster randomised controlled trial of a novel community-based enhanced care intervention to improve person-centred outcomes for people living with HIV/AIDS in Ghana

Study Reference:HR-17/18-7216

I am pleased to inform you that full approval for your project has been granted by the PNM Research Ethics Subcommittee .

For your information, ethical approval has been granted for 3 years from 2 July 2018. If you need approval beyond this point, you will need to apply for an extension at least two weeks before this. You will be required to explain the reasons for the extension. However, you will not need to submit a full re-application unless the protocol has changed.

Ethical approval is required to cover the data-collection phase of the study. This will be until the date specified in this letter. However, you do not need ethical approval to cover subsequent data analysis or publication of the results. For secondary data-analysis, ethical approval is applicable to the data that is sensitive or identifies participants.

Please ensure that you follow the guidelines for good research practice as laid out in UKRIO's Code of Practice for research:
http://www.kcl.ac.uk/innovation/research/support/conduct/cop/index.aspx

Please note you are required to adhere to all research data/records management and storage procedures agreed to as part of your application. This will be expected even after the completion of the study.

If you do not start the project within three months of this letter, please contact the Research Ethics Office.

Please note that you will be required to obtain approval to modify the study. This also encompasses extensions to periods of approval. Please refer to the URL below for further guidance about the process:

http://www.kcl.ac.uk/innovation/research/support/ethics/applications/modifications.aspx

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

If you have any query about any aspect of this ethical approval, please contact the Research Ethics Office:

(http://www.kcl.ac.uk/innovation/research/support/ethics/contact.aspx)

We wish you every success with this work.

Yours sincerely,

Mr James Patterson
Senior Research Ethics Officer

For and on behalf of

Chair of the PNM Research Ethics Subcommittee

Appendix E. GHS ethics approval for study Phase 3

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Tel: +233-302-681109
Fax + 233-302-685424
Email: ghserc@gmail.com

MyRef. GHS/RDD/ERC/Admin/App 118/350
Your Ref. No.

18th July, 2018

Mary Afi Dela Abboah-Offei
Florence Nightingale Faculty of Nursing
Midwifery and Palliative Care King's College
London

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC008/06/18**
Project Title	Phase II Mixed Methods Feasibility Cluster Randomised Controlled Trial of a Novel Community-based Enhanced Care Intervention to Improve Person-Centred Outcomes for People Living with HIV/AIDS in Ghana
Approval Date	18th July, 2018
Expiry Date	17th July, 2019
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report **after completion** of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....
DR. CYNTHIA BANNERMAN
(GHS-ERC CHAIRPERSON)

Appendix F. NOGUCHI ethics approval for study Phase 3

NOGUCHI MEMORIAL INSTITUTE FOR MEDICAL RESEARCH
Established 1979A Constituent of the College of Health Sciences
University of Ghana

INSTITUTIONAL REVIEW BOARD

Phone: +233-302-916438 (Direct)
+233-289-522574
Fax: +233-302-502182/513202
E-mail: nirb@noguchi.ug.edu.gh
Telex No: 2556 UGL GH

Post Office Box LG 581
Legon, Accra
Ghana

My Ref. No: DF.22
Your Ref. No:

4th July, 2018

ETHICAL CLEARANCE

FEDERALWIDE ASSURANCE FWA 00001824 **IRB 00001276**

NMIMR-IRB CPN 004/17-18 *amed. 2018* **IORG 0000908**

On 4th July, 2018, the Noguchi Memorial Institute for Medical Research (NMIMR) Institutional Review Board (IRB) at a full board meeting conducted continuing review and amended your protocol titled:

TITLE OF PROTOCOL : **Development and testing of a novel community-based intervention of integrated palliative care to improve person centred outcomes for people living with HIV/AIDS in Ghana**

PRINCIPAL INVESTIGATOR : **Mary Abboah-Offei, MSc, RN**

Please note that a final review report must be submitted to the Board at the completion of the study. Your research records may be audited at any time during or after the implementation.

Any modification of this research project must be submitted to the IRB for review and approval prior to implementation.

Please report all serious adverse events related to this study to NMIMR-IRB within seven days verbally and fourteen days in writing.

This certificate is valid till 3rd July, 2019. You are to submit annual reports for continuing review.

Signature of Chair: .....
Mrs. Chris Dadzie
(NMIMR – IRB, Chair)

Appendix G. PLWHA participant information for study Phase 2

PARTICIPANTS INFORMATION SHEET FOR PLWHA

REC Reference Number: ----------

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Development and testing of a novel community-based intervention of integrated palliative care to improve person-centred outcomes for people living with HIV/AIDS in Ghana

Invitation
We would like to invite you to participate in this research project which forms part of my PhD research. You should only participate if you want to; choosing not to take part will not disadvantage you in anyway. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
We want to ask about the care that people living with HIV/AIDS (PLWHA) receive from the HIV/AIDS clinic, whether they are easily accessible, or whether they are satisfied with the care they receive or how people living with HIV/AIDS want their care to be delivered.

The findings of this study will be used to develop a new approach to delivering care for people living with HIV/AIDS in the community.

Why have I been invited to take part?
We are asking people living with HIV/AIDS who are aged 20 or over, we expect to recruit 25 people at this clinic.

Do I have to take part?
Participation is voluntary. You do not have to take part. You should read this information sheet and if you have any questions you should ask the research team. You are free to withdraw at any time, you don't have to give a reason. If you are one of the people chosen to be interviewed and you have already been interviewed before you decide to withdraw from the study, you can still decide to remove your data collected.
You can also decide to remove all data about you from the study, up until 31st January 2018. After that time, it will no longer be possible to identify which data is yours.

What will happen to me if I take part?
If you decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. I will then discuss the interview procedure with you and arrange to interview you in a private place (for confidentiality reasons) on the premises where you attend your clinic (or at a suitable venue of your choice if you prefer). We will also look at your records here at West African AIDS Foundation and take some information about your treatment. After this one interview, there will be nothing more for you to do.

The interview will take approximately one hour and be based on the interview topic guide, but it is designed to be flexible so as to meet your needs. The interview will be recorded, subject to your permission. All recordings of data on audio-equipment will be deleted after transcription. Even if you have decided to take part, you are still free to stop your participation at any time during the interview and to have research data/information relating to you withdrawn without giving any reason up to 31st January 2018.

Incentives (where relevant)
If you choose to participate, we will provide GHc10 (equivalent to £2) to pay for your transport and time at this facility.

What are the possible benefits and risks of taking part?
When we finish the study, we will give copies of the final report to West African AIDS Foundation and arrange that you can have a copy if you want.
If you find any of the questions upset you during the research interview you may ask for the interview to stop or speak to the researcher or a member of the clinic team at West African AIDS Foundation about how you feel.
The main disadvantage to taking part in the study is that you will be donating around an hour of your time to take part.

The possible risks you will be exposed to is telling the researcher about your HIV/AIDS and issues that concerns you, which could be distressing for you. If you feel uncomfortable about anything, please inform the researcher or clinic team immediately.

Will my taking part be kept confidential?
Yes. If you consent, any information about you will be kept confidential and secure at Cicely Saunders Institute, King's College London; electronic data on encrypted data sticks, encrypted hard drives or password protected computers and paper records in locked cabinets. Your interview will be anonymised and any identifiable references will be removed in accordance with the Data Protection Act (1998) and research governance. You and your data will not be identifiable in any report or publication.

Personal data will be stored or accessed by the research team for 12 months – 3 years and audio recordings and transcripts will be securely archived for seven years after the study has ended. After this period, all data will be permanently deleted or destroyed. If you withdraw during the study, we will remove your data from the research records according to your wishes.

How is the project being funded?
The project is being funded by the researcher and the Ghana Education Trust Fund.

What will happen to the results of the study?
We will add your response with those from other people at this clinic to find out what issues of concern people living with HIV/AIDS tell us about the care they receive.

After the data collection and once the report is ready, we shall invite all of you to a meeting where we will share the results of the findings. We will also plan to disseminate the research findings through publication and conferences.

Who should I contact for further information?
If you have any questions or require more information about this study, please contact me using the following contact details:

Mary Abboah-Offei (Principal Investigator)
Department of Palliative Care, Policy and Rehabilitation,
Cecily Saunders Institute,
King's College London
Bessemer Road
London UK
SE5 9RJ
Telephone: +233265648267
Email: mary.abboah-offei@kcl.ac.uk

What if I have further questions, or if something goes wrong?
If this study has harmed, you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Dr Richard Harding
Reader in Palliative Care
Department of Palliative Care, Policy and Rehabilitation,
Cecily Saunders Institute,
King's College London
Bessemer Road
London UK
SE5 9RJ
Telephone: +44 (0) 20 78485589
Email: richard.harding@kcl.ac.uk

Thank you for reading this information sheet and for considering taking part in this research.

Appendix H. PLWHA consent form for study Phase 2

CONSENT FORM

Consent Form for PLWHA Interview participants

King's College Research Ethics Committee Ref: _____

Development and testing of a novel community-based intervention of integrated palliative care to improve person-centred outcomes for people living with HIV/AIDS in Ghana

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Please tick

1. I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information and ask questions. ☐
2. I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications, and/or for academic or educational purposes. ☐
3. I understand that my information may be subject to review by relevant individuals from King's College London for monitoring and audit purposes and I understand that such information will be handled and stored in accordance with the terms of the UK Data Protection Act 1998. ☐
4. I understand that my participation is voluntary and that I am free to withdraw at any time, without having to give a reason and without my medical care or legal rights being affected. ☐
5. I agree to take part in the above study and I consent to my interview being audio recorded. ☐
6. I agree that the research team may use my anonymised data for future research. ☐
7. I agree to be approached for further interview. ☐

Participant's Statement:

I _____ *(Participant's name)* agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project and understand what the research study involves.

Signed_____ _____ Date_____

Researcher's signature here indicates witness to thumbprint

Researcher's Statement:

I _____ confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signed _____ Date_____

Appendix I. HCP participant information for study Phase 2

PARTICIPANTS INFORMATION SHEET FOR HCP

REC Reference Number: ----------

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Development and testing of a novel community-based intervention of integrated palliative care to improve person-centred outcomes for people living with HIV/AIDS in Ghana

Invitation

We would like to invite you to participate in this research project which forms part of my PhD research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

We are developing a community-based intervention of integrated palliative care to improve person-centred outcomes for people living with HIV/AIDS in Ghana.

We are conducting this study to help us plan a new approach to HIV/AIDS care in the community. The study will use semi-structured interviews with people living with HIV/AIDS and healthcare professionals to inform the development of a community-based intervention of integrated palliative care that will improve HIV/AIDS care delivery.

We want to understand which aspects of the new intervention are valued by people living with HIV/AIDS and healthcare professionals before we test the intervention a research study. We also want to know how we should deliver the intervention and conduct the research trial, so that both fit in with HIV/AIDS care and other services provided for people living with HIV/AIDS.

Why have I been invited to take part?

You are invited because you are a healthcare professional involved in providing care for people living with HIV/AIDS.

Do I have to take part?

Participation is voluntary. You do not have to take part. You should read this information sheet and if you have any questions you should ask the research team. You are free to withdraw at any time; you don't have to give a reason.

What will happen to me if I take part?

If you decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. I will then discuss the interview procedure with you and arrange to interview you in a private place (for confidentiality reasons) within the clinic. After this one interview, there will be nothing more for you to do.

The interview will take up to 45 to 60 minutes and it will be based on an interview topic guide, which is designed to be flexible. The interview will be recorded, subject to your permission. All recordings of data on audio-equipment will be deleted after transcription. Even if you have decided to take part, you are still free to stop your participation at any time during the interview and to have research data/information relating to you withdrawn without giving any reason up to 31st January 2018.

Incentives (where relevant)

No payment for participation will be made. Although if there are expenses such as travelling cost to the clinic, these can be reimbursed.

Will my taking part be kept confidential?

Yes. If you consent, any information about you will be kept confidential and secure at Cicely Saunders Institute, King's College London; electronic data on encrypted data sticks, encrypted hard drives or password protected computers and paper records in locked cabinets. Your interview will be anonymised and any identifiable references will be removed in accordance with the Data Protection Act (1998) and research governance. You and your data will not be identifiable in any report or publication.

Personal data will be stored or accessed by the research team for 12 months – 3 years and audio recordings and transcripts will be securely archived for seven years after the study has ended. After this period, all data will be permanently deleted or destroyed. If you withdraw during the study, we will remove your data from the research records according to your wishes.

How is the project being funded?

The project is being funded by the researcher and the Ghana Education Trust Fund.

What are the risks and benefits of taking part?

Whilst there are no significant risks, it may distress you to talk about caring for people living with HIV/AIDS. Therefore, we would like to stress that taking part is completely voluntary and you can decide to discontinue at any time.

The potential benefits of participating in the project are to:
Help shape the development of a new intervention
To improve the design of a research study to test the intervention
Reflect on the care you deliver to people living with HIV/AIDS

What will happen to the results of the study?

Findings from the study will be published in scientific journals and reports will be made available for you to access if you wish. We will also plan to disseminate the research findings through publication and conferences. Anonymised data may also be used in future research studies by appropriately qualified researchers, trained and supervised by the research team.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact me using the following contact details:

Mary Abboah-Offei (Principal Investigator)
Department of Palliative Care, Policy and Rehabilitation,
Cecily Saunders Institute,
King's College London
Bessemer Road
London UK
SE5 9RJ
Telephone: +233265648267
Email: mary.abboah-offei@kcl.ac.uk

What if I have further questions, or if something goes wrong?

If this study has harmed, you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Dr Richard Harding
Reader in Palliative Care
Department of Palliative Care, Policy and Rehabilitation,
Cecily Saunders Institute,
King's College London
Bessemer Road
London UK
SE5 9RJ
Telephone: +44 (0) 20 78485589
Email: richard.harding@kcl.ac.uk

Thank you for reading this information sheet and for considering taking part in this research.

Appendix J. HCP consent form for study Phase 2

CONSENT FORM

Consent Form for Healthcare Professionals Interview participants

King's College Research Ethics Committee Ref: _____

Development and testing of a novel community-based intervention of integrated palliative care to improve person-centred outcomes for people living with HIV/AIDS in Ghana

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Please tick

8. I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information and ask questions. ☐

9. I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications, and/or for academic or educational purposes. ☐

10. I understand that my information may be subject to review by relevant individuals from King's College London for monitoring and audit purposes and I understand that such information will be handled and stored in accordance with the terms of the UK Data Protection Act 1998. ☐

11. I understand that my participation is voluntary and that I am free to withdraw at any time, without having to give a reason and without my medical care or legal rights being affected. ☐

12. I agree to take part in the above study and I consent to my interview being audio recorded. ☐

13. I agree that the research team may use my anonymised data for future research. ☐

14. I agree to be approached for further interview. ☐

Participant's Statement:

I _____ *(Participant's name)* agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project and understand what the research study involves.

Signed_____ _____ Date_____

Researcher's signature here indicates witness to thumbprint

Researcher's Statement:

I _____ confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signed _____ Date_____

Appendix K. PLWHA interview guide for study Phase 2

Interview guide for people living with HIV/AIDS (PLWHA)

Section A

INTRODUCTORY STATEMENT:

Thank you for agreeing to participate in a research interview. In this interview, we will be asking you about what matters to you and your health in relation to HIV. We will also ask you some questions about how you want your care to be delivered. As we will be asking you about your identity, your home life, and the care you've received, there may be some questions that you find sensitive. If there are any questions you would rather not answer then we can move on, or if you want to stop the interview at any time, just let me know. Everything you say in this interview will be confidential. The only exception would be if I was concerned for your safety or wellbeing in which case, I would let a member of your care team know that I was concerned, however we would discuss this with you before we disclosed anything. If we use quotes for our research, we will make sure that you cannot be identified from the quote, by replacing names, places and any other identifiable information. I would of course also let you know if this was the case. Do you have any questions before we start?

Section B: Demographics/ sampling frame

Key characteristics	*Response*
ID Code	
Age	
Gender	
Relationship status	
Religion	
Ethnicity/ race	
Occupation	
Education	
Date diagnosed	
ART status	
CD4 count	
Viral load	
Comorbidities	

Section C

Place where you receive standard HIV/AIDS care

1. Tell me, where do you go for your treatment/care?

Prompts

- How often do you go for treatment/care weekly/monthly?
- Do you have any challenges going to your HIV appointments?
- What things can make it difficult for you to attend appointments?
- What stops you from attending appointments?
- What things help you to attend your appointments?
- How easy is it to access your clinic?
- How far do you travel to receive treatment/care?

HIV/AIDS care interactions with clinicians/staff

2. What do you talk about when you attend clinic? What do you ask about? What do you want to ask about?

Prompts

- What do staff ask you about when you come to clinic? What do they talk to you about?
- Are there things you don't feel able to ask about?
- How much time do you spend with staff at the clinic?
- Tell me how long you wait at the clinic before being attended to?
- What dialect do staff use when you attend the clinic? Do you understand that dialect?
- When you attend the clinic do you feel that other PLWHA hear what you discuss with staff? (Do you feel you can tell staff about issues bothering you?)
- Tell me about the support you receive from staff when you fail to attend your appointment?
- What is important to you about the care you receive?
- To what extent do you think staff understand what is important to you?
- What makes you feel they do/ don't?
- How important is it for you that staff understand your priorities?
- Are there any concerns/ problems you have that you think you would not tell the clinic about? Why not?

Living with HIV/AIDS (Physical, Psychological, Social and Spiritual wellbeing)

3. Focusing on you as a person, what are your main issues of concerns living with HIV/AIDS? Do you tell staff? ---------- What do they say/ do? ---------- Do they ask you?

   Prompts

- How does living with HIV/AIDS make you feel?
- How are things at home? Do you have any worries at home?
- Do you receive any religious support? (conditional to religious status in demographics) Why is it important to you? Does your religion impact on how you feel about your HIV?
- How are you feeling in yourself, physically? Tell me about your physical health, symptoms, pain?
- How has your physical health affected your ability to do things day to day at home? Do you tell staff? ---------- What do they say/ do? ---------- Do they ask you?
- Do you think staff care about your social, physical, psychological, spiritual symptoms/ wellbeing?

Person-centeredness and socialization

4. How involved do you feel in the care that you receive at the clinic? Do staff ask your opinion about the care you receive? Do you think you have a role to play in the care staff deliver to you? Do they ask you what matters to you?

   Prompts

- What can you say about the care you receive in this clinic?
- Tell me about a time when you felt you received really good care from the HIV clinic/felt really supported by the HIV clinic?
- How about a time when you felt that the care you received was bad/ felt not supported by staff?
- Can you tell me where you think your idea of good care should be delivered?
- What will make you attend/not attend your HIV/AIDS appointments?
- Can you tell me how keeping your HIV/AIDS appointment affect your social life including working?
- Do you get any support from friends? How often do you see them?

- Are you concerned about friends/others seeing you go for HIV/AIDS treatment/care?

5. If we were to think again about HIV/AIDS services, how could we do things differently?

- To make HIV/ADS care as easily accessible as possible?
- To ensure HIV/ADS care addresses what matters most to you as a person?

Appendix L. HCP interview guide for study Phase 2

Interview guide for Healthcare Professionals (HCP)

Section A

Thank you for agreeing to participate in a research interview. In this interview, we will be asking you about what matters to you and to people living with HIV/AIDS. We will also ask you some questions about how their care is delivered and if there are other better ways to deliver HIV/AIDS care. If there are any questions you would rather not answer then we can move on, or if you want to stop the interview at any time, just let me know. Everything you say in this interview will be confidential. The only exception would be if you raised concerns you had about practices within your team or organisation, where there was a risk of serious harm either to you or to others. In such a situation we would be obliged to report this, however we would discuss this with you before we disclosed anything. If we use quotes for our research, we will make sure that you cannot be identified from the quote, by replacing names, places and any other identifiable information. Do you have any questions before we start?

Section B: Staff demographic data

Characteristics	*Response*
Anonymous ID	
Age	
Gender	
Occupation	
What is your role in the clinic	
How long have you been in this role	

Section C

Working with people living with HIV/AIDS (PLWHA)

6. What brought you to working in HIV/AIDS care?

   Prompts

- How long have you been working with PLWHA?
- Can you tell me about what you do day to day in your job in the clinic?
- Can you tell me about an average day in the clinic?
- Tell me about your motivation to work with PLWHA each day?
- How do you feel working with PLWHA?
- What makes each day in the clinic worthwhile?

HIV/AIDS care delivery

7. What do you think of the current care delivered to PLWHA?

   Prompts

- How many PLWHA do you attend to in a day?
- How much time to you spend with each PLWHA during care appointments?
- What are your priority areas within appointments with PLWHA?
- What discussion do you have with PLWHA about their problems and concerns?
- Apart from CD4 count and viral load suppression, what other outcomes do you think are important for PLWHA?
- What patient reported outcomes are important for PLWHA?

Issues and concerns with regards to HIV/AIDS care in the community

8. Tell me about your issues and concerns in terms of the care you deliver to PLWHA?

   Prompts

- How easy it is for PLWHA to access the clinic?
- What is your views about HIV/AIDS care in the community?
- What do you think are the barriers/ facilitators to the care you deliver to PLWHA?
- How satisfied are you with the care you are able to deliver to PLWHA?
- What is the level of retention in care for PLWHA in this clinic?
- What do you need to support/ successfully manage PLWHA to improve retention?
- What benefits do you think PLWHA derive from this community service?

Concerns and problems of PLWHA (Physical, Psychological, Social and Spiritual)

9. In your view what do you think are the priorities, symptoms and concerns of PLWHA?

   Prompts

- How do you find out about their symptoms and concern?
- What physical symptoms do PLWHA present with at the clinic (pain etc)?
- How do you manage these physical symptoms?
- What psychological symptoms/ issues do PLWHA present with?
- How do you manage these psychological symptoms?
- What emotional and social symptoms (e.g. worries about status disclosure, stigmatisation, family and community relationships etc?) do PLWHA present with at the clinic?
- How do you manage these emotional and social symptoms?
- Tell me about the spiritual symptoms or issues PLWHA discuss with you.
- Does the social, spiritual, psychological and physical symptoms of PLWHA matter to you? If they do, how do you manage them? ..... If they don't why?
- What do they find difficult to manage?
- What would you like to do better?

Person-centred care for PLWHA

10. What are in your view would constitute person-centred care for PLWHA?

    Prompts

- How possible is it to practice person-centred care with PLWHA?
- What are your concerns about providing person-centred care to PLWHA?
- What benefits to you think being person-centred brings to PLWHA?
- What can you say about PLWHA disclosure of personal issues and concerns with you?
- What do you need to enable/ support you to do this?
- Any patient concern they feel are not relevant to the clinic appointment?
- Is there anything you find difficult to ask about?

Adherence and satisfaction with care

11. What is the level of PLWHA adherence and satisfaction with the care they receive here?

    Prompts

- What are the barriers/ promoters of adherence in this clinic?

- What do you think will promote adherence in PLWHA?
- How are you able to tell that the PLWHA are satisfied with the care you provide to them?
- What can you say motivates PLWHA to come to the clinic?

Appendix M. Intervention training content

Cicely Saunders International
Better care at the end of life

WHO Collaborating Centre

KING'S College LONDON

Person-centred communication and holistic needs assessment of the symptom burden of people living with HIV/AIDS in the domains of physical, psychological, social and spiritual wellbeing

Mary Abboah-Offei
PhD cand., MSc, RN.
3rd – 5th September 2018

Training Day 1

Person-centred communication & The holistic approach

3rd September 2018

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Aims of this session

- To improve participants' communication skills
- To teach participants how to use the holistic approach for needs assessment

Learning Objectives

At the end of this session, participants will be able to:

1. Define person-centred communication
2. Explain the importance of person-centred communication
3. Describe the skills needed to communicate effectively
4. Demonstrate good communication skills
5. Explain the holistic approach to needs assessment
6. Conduct a holistic needs assessment

Communication

- Giving and receiving information with the aim of reaching shared understanding
- Important in health care, especially holistic, person-centred care
- Most people have basic communication skills, which are inadequate when providing care to people with complex health issues
- Good communication skills are learned

Communication cycle…

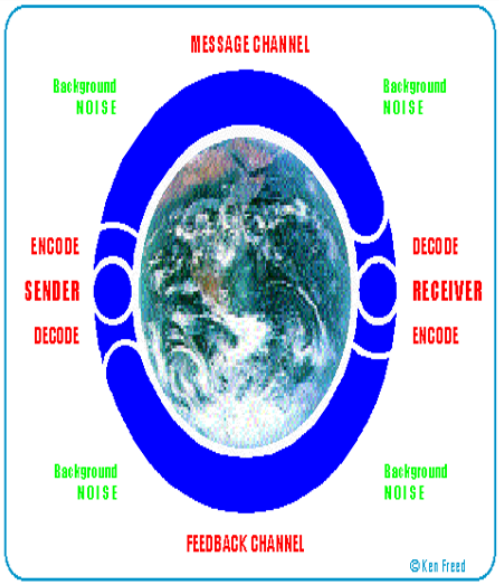
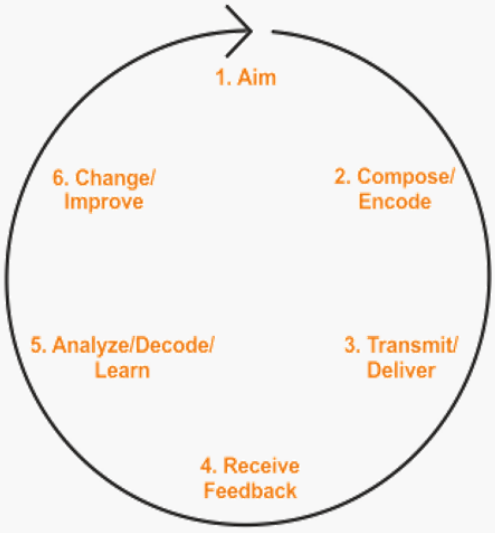


Figure 1: The Communication Cycle



…Communication cycle…

- Encoding
  - the process of transferring the information you want to communicate into a form that can be sent and correctly decoded at the other end.
- Requires
  - ability to convey information clearly and simply,
  - ability to anticipate and eliminate sources of confusion (e.g, cultural issues, mistaken assumptions, & missing information)
  - knowing your audience

…Communication cycle…

- Channel
  - Verbal
  - Non-verbal
  - Written
- Decoding
  - Requires adequate knowledge of receiver

…Communication cycle

- Receiver
  - Has ideas and feelings that influence his/her understanding of a message, and their response.
- Feedback
  - verbal and nonverbal reactions
- Context
  - The situation in which a message is delivered

Why is communication important?

- Good communication:
  - creates trusting relationships
  - gives value to the other person
  - reduces isolation
  - gathers and gives information
  - enables expression of feelings
  - reduces uncertainty
  - maintains hope

Barriers to effective communication

Encoding Barriers

- Lack of Sensitivity to Receiver
- Lack of Basic Communication Skills
- Insufficient Knowledge of the Subject
- Emotional Interference
- Lacking confidence

Transmitting Barriers

- Physical Distractions
- Channel Barriers.
- Long Communication Chain.

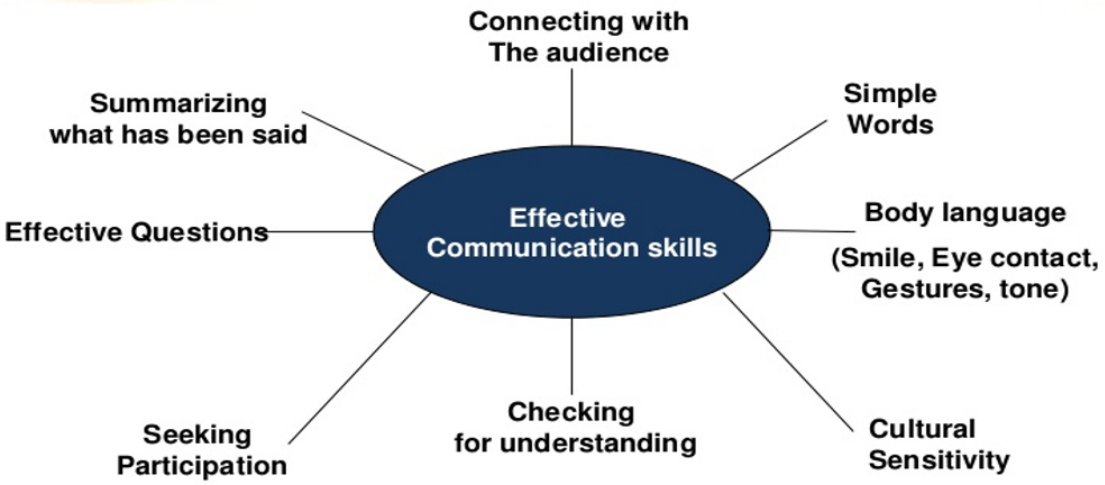
Decoding Barriers.

- Lack of Interest.
- Lack of Knowledge.
- Lack of Communication Skills
- Emotional Distractions
- Information overload
- Conflicting Messages

Responding Barriers

- No Provision for Feedback
- Inadequate Feedback.

Over coming the barriers of effective communication



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Connect with your patient/ Build your Relationship

- Establish rapport:
  - Demonstrate genuine interest, care and respect
  - Greet appropriately
  - Introduce yourself
  - Address patient by name
  - Appropriate non-verbal language
    - Eye contact, open body posture, facial expression, touch
  - Focus fully on patient

Attitudes integral to good communication

- Respect
- Empathy
- Courage
- Intelligence
- Honesty
- Tolerance
- Support
- Sensitivity
- Compassion
- Non-judgmental

People don't care how much you know, until they see how much you care.

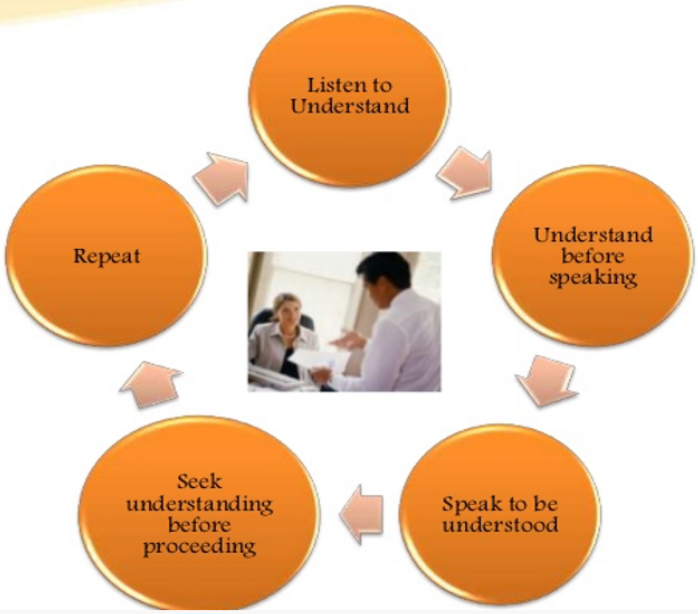
- Lewis Barnett, MD

7 Cs of Communication

The message needs to be

1. Clear.
2. Concise.
3. Concrete.
4. Correct.
5. Coherent.
6. Complete.
7. Courteous.

Path for good communication



Techniques of active listening

PARAPHRASE

Restate what was said in your own words

SUMMARIZE

Pull together the main points of a speaker

QUESTION

Challenge speaker to think further, clarifying both your and their understanding, however suspend judgement

18

Listening for emotion

Communicating skillfully with a patient requires tuning to the patient's emotions and responding appropriately.

Halpern, J. What is Clinical Empathy? J Gen Intern Med. 2003 August; 18(8): 670–674.

Importance of listening

"If we were supposed to talk more than listen, we would have been given two mouths and one ear."

Mark Twain

Essential Elements of Communication in a Medical Encounter

- Open the discussion
- Gather information
- Understand patient's perspectives and context
- Share information
- Reach agreement on problems and plans
- Provide closure

Initiating communication with clients

- Initiating the session
  - Establishing initial rapport
  - Identifying the reason(s) for the consultation
- Gathering information
  - Exploration of patient's problems
  - Encourages patient to express feelings
- Building relationship
  - Using appropriate non-verbal behaviour
  - Developing rapport
  - Involving the patient

The need for person-centred care

- To improve patient experiences and outcomes, and provider satisfaction
- Globally, WHO has developed policy frameworks for people-centred healthcare
- WHO has also highlighted person-centeredness as a core competency of health workers
- Recent policies emphasize the value of patient views…,

"What is important to me about the care I receive is that, I expect staff to ask me about what matters to me each time I come to the clinic, that way the staff will provide support to me based on what matters to me" Male, PLWHA, Age 43.

The holistic approach

Physical

Psychological

Social

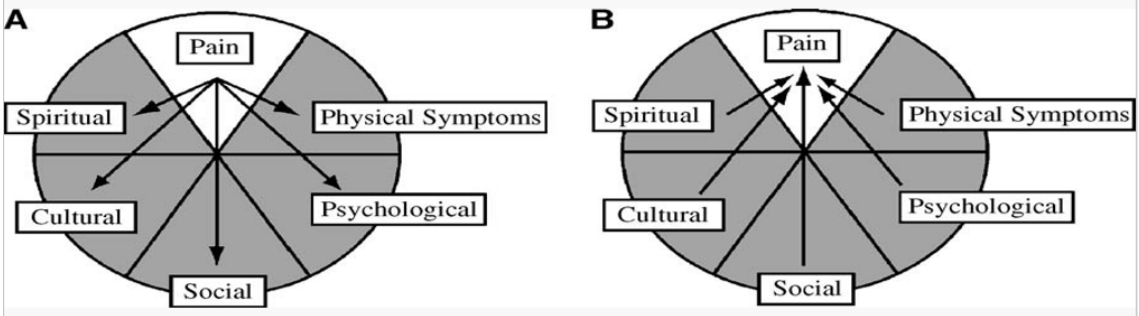
Spiritual

Importance of holistic needs assessment

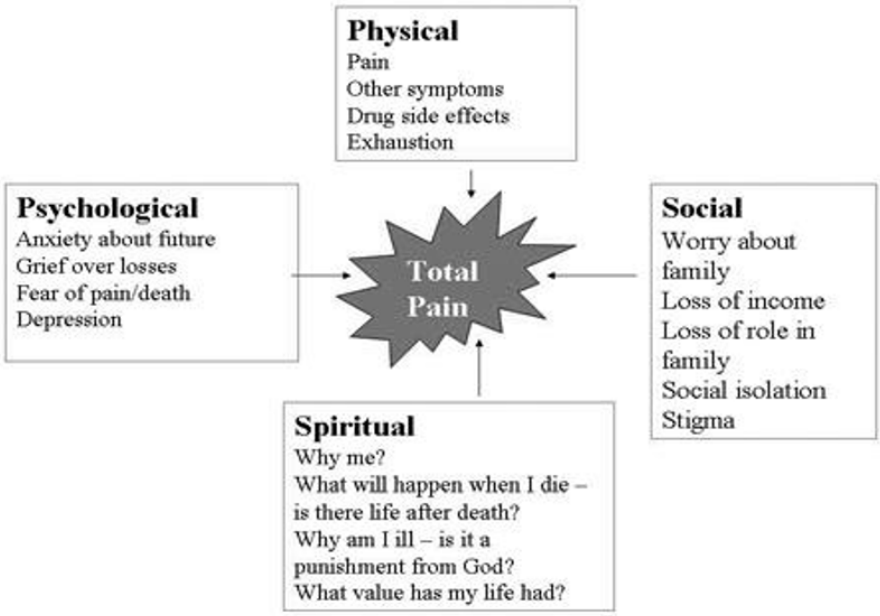
- Psychological problems such as anxiety and depression can worsen many symptoms, e.g. pain, breathlessness.
- Physical problems can worsen psychological ones, e.g. pain can lead to depression.
- Social problems, e.g. lack of income or loss of carers, affects physical and psychological wellbeing.
- Spiritual issues affect psychological and social wellbeing

Importance of holistic needs assessment

Interdependence of the various causes of suffering



Total pain



***Role play**: Kate is a 30-year-old mother of three children. She has been nursing her husband Harry, who was diagnosed with prostate cancer 10 years ago. Recently she found out that on top of the cancer, Harry also has AIDS. She is very angry with him and threatens to run away with her children and leave Harry to suffer. However, before leaving, she decides to come to the clinic where Harry is receiving treatment, for help. She wants to find out if she has AIDS and what she can do to take care of herself and the children.*

Training Day 2

PSYCHOSOCIAL WELLBEING

4th September 2018

Learning objectives

By the end of the module we should be able to:

- Describe psychological problems people living with HIV/AIDS experience
- Describe how to carry out a psychological assessment
- Discuss how to give psychological support

Introduction….

- It is important to understand that the mind and emotions impact on the immune system and quality of life.
- People living with HIV have several psychosocial issues they deal with.

Quality of life

- Think about your own quality of life.
  - Do you have the ability to work?
  - What is your daily energy level?
  - What is your diet like?
  - Do you enjoy your social life?
  - What about your sex life?
  - Is your self-image positive or negative?
- Stop. Now, think about how these concerns might affect a PLWHA differently….

Discussion Point

- What Psychosocial issues do PLWHA experience at diagnosis?

Grief and Loss

- They may feel a profound sense of grief and loss on many levels, for prolonged periods
- If this grief is not addressed, it can lead to:
  - feelings of helplessness,
  - high risk behaviour,
  - a lack of medical care, and
  - acting out with intense emotions.

Stigma & Discrimination…

- A lot of stigma, shame & misinformation surrounds HIV/AIDS
- The stigma itself creates issues to deal with separate from the medical diagnosis.
- Misconceptions about HIV/AIDS include:
  - Drug user
  - MSM
  - Multiple partners
  - Punishment from God
  - Deserve to get this disease
  - Prostitute

…STIGMA

- Stigma can prevent people from acknowledging HIV as a major cause of illness and death.
- It can prevent PLWHA from:
  - seeking counselling,
  - obtaining medical and
  - psychological care, and
  - taking preventative measures to avoid passing the virus on to others.
- Prevention behaviours may carry stigma.

Self Esteem & Self Criticism

- PLWHA can experience a drop in self esteem because of:
  - The stigma associated with HIV being a sexually transmitted disease
  - Questioning oneself--"What did I do to deserve this?"
  - Internalizing homophobia-- "because I am MSM, I got HIV"
  - Beginning to see oneself as "toxic" to others

Social Isolation

- PLWHA might worry about telling their families & other relationships
- Some family and friends might choose to withdraw because of:
  - Fear of death
  - Helplessness
  - Fear of “catching” HIV/AIDS
  - Shame and pressure from the stigma

PLWHA worry about ……

- Who will stand by me?
- What effect will it have on my current relationship?
- Will I still find love?
- Can I still date other people?
- Will I be disowned by my family or treated differently?
- What will my friends say?

PLWHA worry about jobs

- Will I be fired if someone at work finds out?
- How do I explain calling of sick a lot?
- When will I have to stop working?
- How will I support myself and my family?

Effects on intimacy & sexual relationships

- Living with HIV/AIDS can be a barrier to having intimate or sexual relationships.
- Self isolation can increase a sense of depression and complicate intimacy and sexual relationships.

Confidentiality & disclosure of status

- PLWHA worry about confidentiality.
- Deciding who and when to tell is not easy.
- Some concerns might be:
  - Should I just keep this to myself?
  - How do I get help without everyone finding out my status?
  - How do I tell my loved ones?
  - What can I do to assure a safe home, work and social life?

Depression & HIV/AIDS

- Depression is a mood disorder.
- It is more than just feeling sad or grieving. It is more intense and lasts longer. Depression can be linked to:
  - Events in your daily life
  - Chemical changes in the brain
  - Side effects of required medications
  - Several physical disorders
- Rates of depression among PLWHA are as high as 60%, as opposed to 5-10% of the general population.

Anxiety disorders & HIV/AIDS

- Anxiety can develop because of a person's
  - uncertainty about HIV infection & treatment, or
  - issues unrelated to HIV.
- Symptoms can include:
  - Mild distress
  - Major panic attacks
  - Excessive worrying

Substance abuse & HIV/AIDS

- Some PLWHA may use substances for a variety of reasons:
  - To help control or counteract side effects of medications
  - To socialize
  - As part of a process of harm reduction
  - To escape
  - To self-medicate for mental health problems

Substance abuse concerns

- Interactions with prescribed medications
- Possible overdose
- Addiction
- Non-adherence to treatment
- Housing and/or poverty issues
- Missing healthcare appointments

Suicide and HIV/AIDS

- Many events can trigger suicidal thoughts among PLWHA, these can include:
  - Learning of their positive HIV status
  - Noticing the first symptoms
  - Starting ART
  - Fear of disclosing to family and friends
  - Losing a significant relationship
  - Losing a job
  - Experiencing major changes in lifestyle

Psychosocial needs assessment

- Psychological assessment should be carried out at key points in the life of PLWHA, and assess risk of harm to self and others, for example:
  - at times of HIV diagnosis
  - at initial onset of physical symptoms
  - when there are changes in blood counts
  - when starting antiretroviral therapies
  - at times of non-adherence at the development of side-effects
  - at the development of relationship difficulties

Psychosocial assessment contd: Depression…

Have you been bothered by:

- Little interest or pleasure in doing things?
- Feeling depressed, hopeless feeling or sad?
- Feeling worried?
- Trouble falling asleep or sleeping too much?
- Feeling tired or having little energy poor appetite or overeating, feeling irritable?

…Assess depression

- Feeling bad about yourself – that you are a failure or have let yourself or your family down?
- Trouble concentrating on things?
- Moving or speaking so slowly other people could notice, or being very fidgety?
- Restless or feeling nervous?
- Thoughts that you would be better off dead or of hurting yourself in some way?

Managing psychosocial problems

- Practical support and assistance
  - Increasing one's social network
  - Spending time with friends & family
- Professional counselling
  - Individual therapy
  - Support groups
- Education
  - Learning to manage the disease and continue to enjoy life
- Psychotherapy & psychiatric care (refer PLWHA)

Ways to show support

- Explicitly offer support. People don't always come out and ask for help on their own.
- Listen without giving advice.
- Respect choices/decisions
- Offer to be an advocate
- Help to find resources
- Talk with your superior regarding specific concerns and be familiar with your clinic policies.

In summary…….

***Role play**: Lilly, a 10-year-old girl, was born with HIV. She is a total orphan under the care of her maternal aunt, who herself lost her husband due to AIDS. Lilly was neglected by her paternal relatives after they realised that she was HIV positive. Lilly's caregiver, her aunt, has six biological children and they live in a single rented room. The caregiver earns a living through brewing and selling the local brew. She is a drunkard and sometimes beats Lilly. Lilly has not been very well since late last year and has stopped school for some time because of this. A Samaritan brought Lilly and her caregiver to the clinic, assess and identify their psychosocial issues and offer support.*

Training Day 3

PHYSICAL & SPIRITUAL WELLBEING

5th September 2018

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Learning objectives:

- Describe how to carry out pain assessment
- Discuss the use of pain assessment tools
- Discuss what is meant by 'spirituality' & the importance of spiritual support in HIV care
- Explain what is meant by the 'HOPE' checklist

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What is pain?

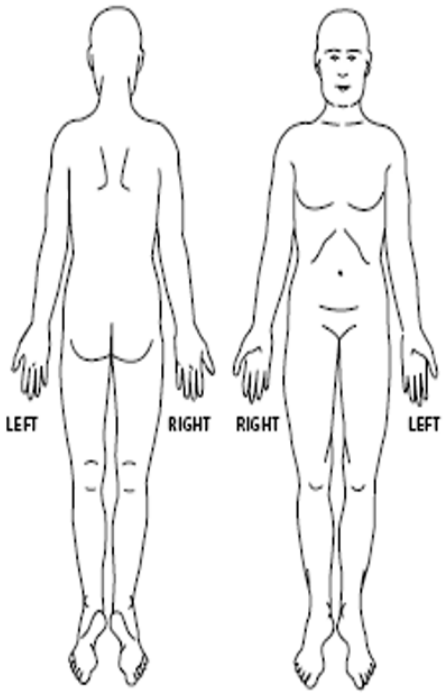
- Pain is what the PLWHA says hurts
- Over 70% of people with HIV disease experience pain.

Importance of pain assessment

- Pain in PWLHA is often dealt with poorly
- Pain often remains undiagnosed and inadequately treated leading to complications
- Careful assessment of pain is essential to identify causes of pain that can be treated
- Pain assessment helps to determine what type of pain it is and how it can best be managed

Seven important questions to ask…

1. Where is the pain? (there may be >1)
2. When did it start?
3. What does it feel like? (stabbing, burning)
4. Is the pain there all the time?
5. Has any treatment been tried?
6. What makes it better or worse?
7. What do you think is causing the pain?



Where is the pain?

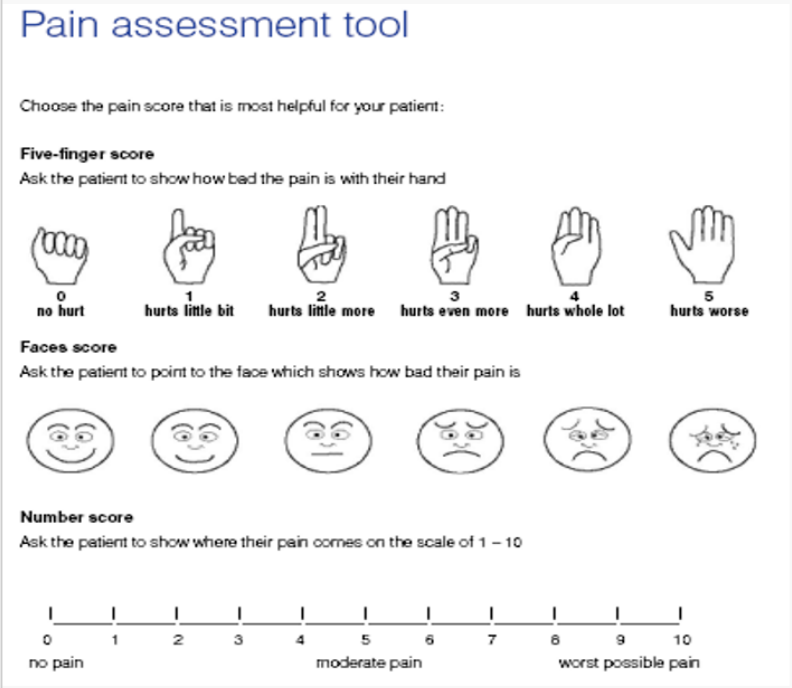
Key Questions

Where is the pain?

Can you point to it?

Does it spread?

What effect is the pain having?



Use tools to assess pain severity. Select tools based on the patient

What effect is the pain having?

Does it prevent normal activity?

- preventing sleep?
- preventing movement such as walking?
- preventing sitting down?
- preventing eating or swallowing?
- other suggestions?

One extra question

- What does the pain mean to you?
- Some answers
  - I am being punished
  - I have HIV
  - I am going to die
  - There is no hope
  - I cannot live my normal life
  - I have to suffer, it is my destiny
  - I am being eaten away

What relieves the pain?

- Better when staying still
- Better when bowels are open
- Better if use hot or cold compress
- Better if praying
- Better when with friends
- Better when taking painkillers

Assessment of other symptoms

- Could you tell me five worst symptoms you have experienced in the past five days? For example: nausea or vomiting, pain, lack of energy, lack of appetite, constipation, difficulty in sleeping, shortness of breath, dizziness.
- Difficulty seeing/ hearing/ moving/ walking etc.
- Others




In physical assessment….

- Accurate assessment involves detailed history and examination
- Choice of pain rating scales depend on patients understanding
- Baseline pain score is important
- Remember holistic assessment and total pain
- Re-assessment is an essential part of good care

Spiritual wellbeing

- Spirituality and religious beliefs may be increasingly important to people living with HIV/AIDS.
- Supporting the spiritual needs of PLWHA and their families is a critical component of compassionate care.
- It can engender hope.

What is spirituality?

- Reflect
- Write thoughts / answers
- Share

Spirituality

- Meaning
  - Who am I?, Why am I here?, What is life about?
- Transcendence
  - belief in God / spiritual powers / afterlife
- Harmony
  - at peace with others, forgiveness, connectedness

Why is spirituality important in HIV care?

- Helps PLWHA to make peace with their maker
- Finds meaning to life
- Makes life worth living

What question do people ask?

- Why has this happened to me?
- What is the meaning of my life?
- Why did God allow this?
- Is there a God who cares?
- What is the point of it all?
- Am I being punished?
- What/who has caused this suffering?
- What will happen after I die?

…Spiritual assessment

Awareness of underlying issues and asking questions like:

- What do you have to help you cope?
- Do you have a faith to support you?
- Do you feel frightened of the future?
- Are you at peace with God?
- What gives you hope / meaning?

Different aspects of spirituality: the HOPE checklist

- H - **Hope** –what are the sources of hope, meaning, and peace for that person
- O **Organised religion** – what is its role for that person
- P- **Problems/ issues/ questions** they are facing
- E- **Effect on care** – how would they want their spirituality to be incorporated treatment/illness

….Offering Spiritual Support

- Providing a place where they can reflect/ pray
- Providing things such as a Bible, Koran, etc.
- Reading their scriptures to them
- Arranging for certain rituals to be carried out, e.g. Holy Communion
- Playing music which they find helpful
- Finding a faith leader from their own religion to visit
- Arranging for them to go to their place of worship

***Role play**: Sheka, a 49 year old male and father of four children, has HIV/AIDS and has been on ART for the last four years. However, over the last two months his condition has deteriorated. He looks emaciated, he is very weak and his skin is rough. He has developed painful multiple swellings on the lower limbs. He is not eating regularly because of the severe pain that he experiences on swallowing both solids and liquids. Recently, he lost his job due to absenteeism as a result of the general weakness he is experiencing. He is very worried about his children's school fees and house rent. He has also lost hope to live. Assess Sheka's physical issues; and use the HOPE checklist to assess his spiritual issues.*

In conclusion.....

"Man is not destroyed by suffering; he is destroyed by suffering without meaning"

Victor Frankl

Appendix N. Holistic assessment tool for study Phase 3

Patient's name ---------- Date ----------

PHYSICAL ASSESSMENT

Pain

Ask the patient to show where their pain comes on the scale of 0-5

0 1 2 3 4 5

Important questions to ask the patient

- Where is the pain (there may be more than one pain)?
- When did it start?
- What does it feel like? (e.g. stabbing, cramping, burning etc.)
- Timing – is the pain there all the time
- Or does it come and go?
- Does the pain cause you to wake up at night?
- Treatment – has any treatment been tried and has it helped?
- Change – what makes it better or worse (e.g. movement, eating, time of day etc.)?
- Cause – what do you (the patient) think is causing the pain?

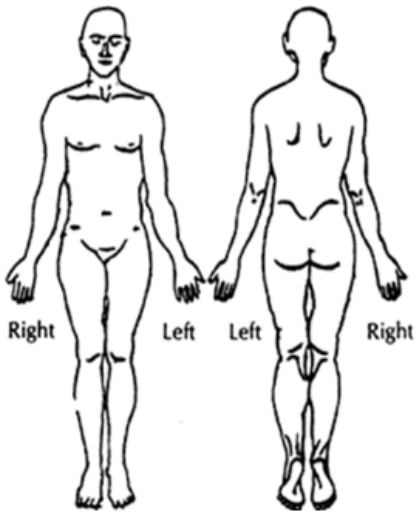
Pain assessment comments:

Body Chart

Mark on and describe sites of pain and symptoms

Include:

- Chest
- Abdomen
- Neurological



Body chart assessment comments:

Assessment of other physical symptoms

Could you list the five worst symptoms you have experienced in the past five days? For example:

- Nausea or vomiting
- Lack of energy
- Lack of appetite
- Constipation
- Difficulty in sleeping
- Shortness of breath
- Dizziness
- Difficulty seeing/hearing/moving/walking etc

Other physical assessment comments:

PSYCHOLOGICAL ASSESSMENT

Over the last two weeks have you been bothered by:

- Little interest or pleasure in doing things
- Feeling depressed or hopeless
- Feeling sad
- Feeling worried
- Trouble falling asleep or sleeping too much
- Feeling tired or having little energy
- Poor appetite or overeating
- Feeling irritable
- Feeling bad about yourself – that you are a failure or have let yourself or your family down?
- Trouble concentrating on things?
- Moving or speaking so slowly other people could notice,
- Being very fidgety and restless
- Feeling nervous
- Thoughts that you would be better off dead or of hurting yourself in some way?

If you have been bothered by any of these problems, how difficult have they made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all ***Somewhat difficult*** ***Very difficult*** ***Extremely difficult***

Psychological assessment comments:

SOCIAL ASSESSMENT

Understanding of illness and consequences

- What do you understand by your illness?
- What does your family understand?
- What is your main distress?
- What is your family's main distress? What are your expectations?
- What are the family's expectations?
- Has the illness affected any close relationships? (this may include sexual issues)
- What would help you to live well with your HIV and to be able to benefit from your treatment?

Understanding of illness assessment comments:

Activities of daily living

	Independent	**Needs assistance**	**Dependent**
Bathing			
Dressing			
Toilet			
Mobility			
Continence			
Feeding			

Activity of daily living assessment comments:

Family support (discuss)

Have you disclosed your HIV status to your family? Are they supportive?

- Financially
- Emotionally
- Socially
- Spiritually
- Are there any problems?

Family support assessment comments:

Economic situation (discuss)

- Employment
- Income
- Accommodation
- Medical Insurance
- Other expenses

Economic situation assessment comments:

SPIRITUAL ASSESSMENT

Discuss:

- **Faith** – What do you believe has brought meaning to your life?
  Do you have a faith or belief?
- **Importance** – How important is your faith or spirituality to you?
  How is it important?
  Importance of religion/faith or belief system in life (please circle)
  Great **Moderate** **Unimportant** **Nil**

- **Community** – Are you part of a religious or spiritual community? If you don't have a community, would it help you if you found one? Do you pray with others?
  Does it help you? Would you like to give us your religious adviser contact number so we can assist you in contacting them?
- **Peace** - Are you at peace with your faith or belief?
  Are you at peace with your family?
- **Address or Application** – Can we help in any way? How would you like me to address these issues in your healthcare? How do these issues impact your current situation? Do you have any fears or concerns regarding your spirituality which we may be able to address? Has your illness in any way affected your faith or belief? Would it help to see a pastor/imam/spiritual counsellor?

Spiritual assessment comments:

Appendix O. Care plan template used to plan care for study Phase 3

Participant ID ---------- Care plan for Community-based enhanced care intervention participant

Symptom/ concern	Concern code	PLWHA goals of care and treatment goal	Actions required	Person/ People responsible	Review date	Goals achieved	What I still want to achieve

Concern code: 1. Physical symptoms (e.g. pain, fatigue, cough, nausea, vomiting, lack of sleep)
2. Psychological distress (e.g. anger, guilt, worry, depression)
3. Social issues (e.g. family role, relationship issues, employment, finances)
4. Spiritual concern (e.g. Being at peace, with self/ supreme being & existential issues)
5. Other concerns (e.g. support, ART)

Name of HCP completing ----------
Role ----------
Signature ----------
Date and time ----------

Appendix P. PLWHA participant information for study Phase 3

PARTICIPANT INFORMATION

FEASIBILITY CLUSTER RCT

REC Reference Number: HR-17/18-7216

Phase II mixed methods feasibility cluster randomised controlled trial of a novel community-based enhanced care intervention to improve person-centred outcomes for people living with HIV/AIDS in Ghana

You will be given a copy of this information sheet

We would like to invite you to take part in this original research project which is being conducted for the award of a PhD at King's College London. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

We have developed a community-based intervention of integrated Enhanced care to improve person-centred outcomes for people living with HIV/AIDS in Ghana. We are doing a small study to find out whether it is possible to recruit and retain participants if we decide to conduct a larger study in future.

Why have I been chosen?

We are asking all people living with HIV/AIDS who are aged 20 and over, and have been living with HIV/AIDS for at least six months. We hope for 30 people in this clinic to take part.

Do I have to take part?

No, you don't have to take part. If you decide to, you are free to withdraw at any time, and you don't have to give a reason. If you decide to withdraw from the study, you will still have the care and support for all the time you would have

been in the study. You can also decide to remove all data about you from the study, up until 31st December 2018. After that time, it will no longer be possible to identify which data is yours.

What will happen if I take part?

You will be given this information to keep if you wish and asked to sign a consent form to show that you have agreed to participate. The researcher will ask you to complete six questionnaires, which will take about one hour altogether.

One clinic of the two clinics will continue to deliver standard care and the other clinic will deliver the enhanced care intervention. We will train healthcare professionals in one clinic of the two to deliver the enhanced care intervention. Therefore, you will not know which of the clinics that will deliver the enhanced care intervention. Whether you receive standard care or the enhanced care intervention it will be delivered by your usual staff at your usual clinic. You will be asked to complete six questionnaires each month for three months with the researcher which will take about one hour. After three months the research will be over, and you will continue to receive at your usual clinic.

The questionnaires are about how you feel and what care you have had. Some of the topics include:

- Physical problems like pain and symptoms
- How you are feeling emotionally
- What kinds of care you have received from the clinic?

While taking part, you may be exposed to potential risks such as psychological, emotional or personal harm including disclosure of sensitive information. You can ask to take a break or stop the interview at any time. Everything you say will be completely private and confidential unless the interviewer thinks you or your family's safety is at risk. If this happens, they may have to tell someone in your care team who can ensure safety. This will not be done without discussing it with you first.

Are there any other effects of being in the study?

If you choose to participate, we will provide GHc12.50 (equivalent to £2) to pay for your transport to get to the clinic. When we finish the study, we will give copies of the final report to the clinic and arrange that you can have a copy if you want.

Will my taking part in this study be kept confidential?

All the information which we collect during the interview will be kept strictly confidential and anonymous. You will not be identified in any way, and your personal details (for example name and address will be kept separately from the information you give. We will NOT let anyone have any information that could identify you. Any information you give will NOT be kept with anything that could identify you (like your name or address). You may withdraw your data from the study at any time up until January 2019. Everything you say will be completely private unless the researcher thinks you or family's safety is at risk, in which case the may have to tell your care team. The researcher will tell you that they have concerns before speaking to the care team.

What happens to the result of the research study?

The result of this study will be shared with the two clinics which you can access a copy if you want. We will also feedback the findings of this study to policy makers and to also disseminate the findings through peer review publications and research conferences.

Who is organising the research?

This study is being organised by King's College London (UK). The Ghana Health Service Research Ethics Committee, Noguchi Memorial Institute for Medical Research Institutional Review Board and King's College London Research Ethics Committee have reviewed this study and approved it for your protection.

Who can I contact?

If you would like to talk to someone about the study, or get more information, or if you have experienced any harm as a result of this study, have any questions or require more information about this study, please contact:

Mary Abboah-Offei (Principal Investigator)
Cicely Saunders Institute of Palliative Care, Policy & Rehabilitation
Florence Nightingale Faculty of Nursing, Midwifery & Palliative care
King's College, London
Bessemer Road, Denmark Hill
London, SE5 9PJ
Telephone: +233544635508

Professor Richard Harding (Academic supervisor)

Cicely Saunders Institute of Palliative Care, Policy & Rehabilitation

Florence Nightingale Faculty of Nursing, Midwifery & Palliative care

King's College, London

Bessemer Road, Denmark Hill

London, SE5 9PJ

Telephone: +44 (0) 20 78485589

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

The Chair, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee Chair, rec@kcl.ac.uk

Local contacts:

1. Dr Naa Ashiley Vanderpuye,
   Chief Executive Officer - West Africa AIDS Foundation (WAAF)
   Plot 650, Ecomog Road Haatso,
   Ga East District, Greater Accra.

2. Dr Gloria A. Ansa MBChB MBA PhD (Leeds)
   Head of Public Health and Research
   University of Ghana Health Services,
   University of Ghana, Legon.

Thank you for reading this information sheet and for considering taking part in this research.

Appendix Q. PLWHA consent form for study phase 3

CONSENT FORM

FEASIBILITY CLUSTER RCT

King's College Research Ethics Committee Ref: _____

Phase III mixed methods feasibility cluster randomised controlled trial of a novel community-based Enhanced care to improve person-centred outcomes for people living with HIV/AIDS in Ghana

Please complete this form after you have read the Information Sheet and/ or listened to an explanation about the research.

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Please tick

15. I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be treated as strictly confidential and will be handled in accordance with the terms of the UK Data Protection Act 1998. ☐

16. I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data at any time up to January 2019. ☐

17. I agree that the research team or other researchers may use my data for future researchand understand that any such use of identifiable data would be reviewed and approved by a research ethics committee (In such cases, as with this project, data would not be identifiable in any report). ☐

Participant's Statement:

I _____ *(Participant's name)* agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project and understand what the research study involves.

Signed ---------- Date ---------- *Researcher's signature here*
Indicates witness to thumbprint

Researcher's Statement:

I _____ confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signed _____ Date_____

Appendix R. Participant screening log for study Phase 3

KING'S College LONDON

LEGON CLINIC SCREENING LOG A community-based enhanced care intervention for people living with HIV/AIDS

Client ID	Gender	Age	Approached Y/N	Exclusion criteria 1 = For pre-counselling & testing 2 = Too ill to participate 3 = Below 20 years 4 = Diagnosed <6months 5 = Cognitive impairment 6 = Other (give reason)	Name of person making approach	Date participant information sheet given	Date of decision to/ not to participate	Reason for decline: 1 = Not interested 2 = Does not have time 3 = Already in another study 4 = Not eligible 5= Other (choose all that apply)	Remarks
SL1	F	34	Y	-	MA-O	18.07.18	18.07.18	-	Recruited
SL2	F	46	Y	-	MA-O	18.07.18	18.07.18	-	Recruited
SL3	F	32	Y	-	MA-O	18.07.18	18.07.18	2	Declined
SL4	M	29	Y	-	MA-O	18.07.18	18.07.18	-	Recruited
SL5	M	17	Y	3	MA-O	20.07.18	20.07.18	4	Not eligible
SL6	F	61	Y	-	MA-O	20.07.18	20.07.18	-	Recruited
SL7	M	37	Y	-	MA-O	20.07.18	20.07.18	-	Recruited
SL8	M	29	Y	-	MA-O	20.07.18	20.07.18	2	Declined
SL9	M	25	Y	-	MA-O	25.07.18	25.07.18	-	Recruited
SL10	M	68	Y	-	MA-O	25.07.18	25.07.18	-	Recruited
SL11	M	41	Y	-	MA-O	25.07.18	25.07.18	-	Recruited
SL12	F	54	Y	-	MA-O	25.07.18	25.07.18	1	Declined
SL13	F	25	Y	-	MA-O	27.07.18	27.07.18	-	Recruited
SL14	F	30	Y	-	MA-O	27.07.18	27.07.18	-	Recruited
SL15	M	46	Y	-	MA-O	27.07.18	27.07.18	-	Recruited
SL16	M	37	Y	-	MA-O	27.07.18	27.07.18	-	Recruited
SL17	F	23	Y	1	MA-O	01.08.18	01.08.18	4	Not eligible
SL18	F	51	Y	-	MA-O	01.08.18	01.08.18	-	Recruited
SL19	F	31	Y	-	MA-O	01.08.18	01.08.18	-	Recruited

SL20	M	56	Y	-	MA-O	01.08.18	01.08.18	-	Recruited
SL21	M	47	Y	-	MA-O	03.08.18	03.08.18	-	Recruited
SL22	F	21	Y	4	MA-O	03.08.18	03.08.18	4	Not eligible
SL23	M	32	Y	-	MA-O	03.08.18	03.08.18	-	Recruited
SL24	M	29	Y	-	MA-O	03.08.18	03.08.18	-	Recruited
SL25	F	40	Y	-	MA-O	08.08.18	08.08.18	1	Declined
SL26	F	40	Y	-	MA-O	08.08.18	08.08.18	-	Recruited
SL27	F	23	Y	-	MA-O	08.08.18	08.08.18	-	Recruited
SL28	M	57	Y	5	MA-O	08.08.18	08.08.18	4	Not eligible
SL29	M	40	Y	-	MA-O	08.08.18	08.08.18	-	Recruited
SL30	F	60	Y	-	MA-O	10.08.18	10.08.18	-	Recruited
SL31	M	28	Y	4	MA-O	10.08.18	10.08.18	4	Not eligible
SL32	F	45	Y	-	MA-O	10.08.18	10.08.18	-	Recruited
SL33	F	26	Y	-	MA-O	10.08.18	10.08.18	-	Recruited
SL34	M	38	Y	-	MA-O	15.08.18	15.08.18	-	Recruited
SL35	M	31	Y	-	MA-O	15.08.18	15.08.18	-	Recruited
SL36	M	37	Y	-	MA-O	15.08.18	15.08.18	-	Recruited
SL37	F	44	Y	-	MA-O	15.08.18	15.08.18	-	Recruited
SL38	F	43	Y	4	MA-O	17.08.18	17.08.18	4	Not eligible
SL39	F	30	Y	-	MA-O	17.08.18	17.08.18	-	Recruited
SL40	M	28	Y	-	MA-O	17.08.18	17.08.18	-	Recruited
SL41	M	54	Y	-	MA-O	17.08.18	17.08.18	1	Declined

KING'S College LONDON

WAAF SCREENING LOG A community-based enhanced care intervention for people living with HIV/AIDS

Client ID	Gender	Age	Approached Y/N	Exclusion criteria 1 = For pre-counselling & testing 2 = Too ill to participate 3 = Below 20 years 4 = Diagnosed < 6months 5 = Cognitive impairment 6 = Other (give reason)	Name of person making approach	Date participant information sheet given	Date of decision to/ not to participate	Reason for decline: 1 = Not interested 2 = Does not have time 3 = Already in another study 4 = Does not meet criteria 5= Other (choose all that apply)	Remarks
SW1	M	28	Y	-	MA-O	24.07.18	24.07.18	-	Recruited
SW2	F	62	Y	-	MA-O	24.07.18	24.07.18	-	Recruited
SW3	M	18	Y	3	MA-O	24.07.18	24.07.18	4	Not eligible
SW4	F	35	Y	-	MA-O	26.07.18	26.07.18	2	Declined
SW5	F	31	Y	-	MA-O	26.07.18	26.07.18	-	Recruited
SW6	F	62	Y	-	MA-O	26.07.18	26.07.18	-	Recruited
SW7	F	32	Y	1	MA-O	26.07.18	26.07.18	4	Not eligible
SW8	M	26	Y	-	MA-O	30.07.18	30.07.18	-	Recruited
SW9	M	45	Y	-	MA-O	30.07.18	30.07.18	-	Recruited
SW10	F	47	Y	-	MA-O	30.07.18	30.07.18	-	Recruited
SW11	F	43	Y	-	MA-O	31.07.18	31.07.18	1	Declined
SW12	M	26	Y	-	MA-O	31.07.18	31.07.18	-	Recruited
SW13	F	35	Y	-	MA-O	31.07.18	31.07.18	-	Recruited
SW14	M	16	Y	3	MA-O	31.07.18	31.07.18	4	Not eligible
SW15	F	26	Y	-	MA-O	31.07.18	31.07.18	-	Recruited
SW16	F	34	Y	-	MA-O	02.08.18	02.07.18	-	Recruited
SW17	M	48	Y	-	MA-O	02.08.18	02.08.18	2	Declined
SW18	F	41	Y	-	MA-O	02.08.18	02.08.18	-	Recruited
SW19	M	37	Y	-	MA-O	02.08.18	02.08.18	-	Recruited
SW20	M	40	Y	-	MA-O	02.08.18	02.08.18	-	Recruited
SW21	F	41	Y	4	MA-O	02.08.18	02.08.18	4	Not eligible

SW22	F	32	Y	-	MA-O	06.08.18	06.08.18	-	Recruited
SW23	F	52	Y	-	MA-O	06.08.18	06.08.18	-	Recruited
SW24	F	17	Y	3	MA-O	06.08.18	06.08.18	4	Not eligible
SW25	F	29	Y	-	MA-O	06.08.18	06.08.18	-	Recruited
SW26	M	24	Y	-	MA-O	06.08.18	06.08.18	1	Declined
SW27	F	38	Y	-	MA-O	07.08.18	07.08.18	-	Recruited
SW28	F	30	Y	-	MA-O	07.08.18	07.08.18	-	Recruited
SW29	M	32	Y	-	MA-O	13.08.18	13.08.18	-	Recruited
SW30	M	24	Y	1	MA-O	13.08.18	13.08.18	4	Not eligible
SW31	F	32	Y	-	MA-O	14.08.18	14.08.18	-	Recruited
SW32	M	55	Y	-	MA-O	14.08.18	14.08.18	-	Recruited
SW33	F	28	Y	-	MA-O	14.08.18	14.08.18	-	Recruited
SW34	F	40	Y	-	MA-O	14.08.18	14.08.18	-	Recruited
SW35	F	37	Y	4	MA-O	14.08.18	14.08.18	4	Not eligible
SW36	F	40	Y	-	MA-O	20.08.18	20.08.18	-	Recruited
SW37	F	26	Y	-	MA-O	20.08.18	20.08.18	-	Recruited
SW38	M	36	Y	-	MA-O	20.08.18	20.08.18	-	Recruited
SW39	F	30	Y	-	MA-O	20.08.18	20.08.18	-	Recruited
SW40	F	44	Y	-	MA-O	22.08.18	22.08.18	-	Recruited
SW41	F	18	Y	3	MA-O	22.08.18	22.08.18	4	Not eligible
SW42	M	39	Y	-	MA-O	22.08.18	22.08.18	-	Recruited

Appendix S. Intervention training certificates

Cicely Saunders International
Better care at the end of life

KING'S College LONDON
University of London

CERTIFICATE OF ATTENDANCE

This is to certify that

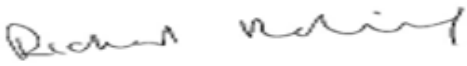
Attended the following training course

Person-centred Communication and Holistic Needs Assessment of the Symptom Burden of People Living with HIV/AIDS in the Domains of Physical, Psychological, Social and Spiritual Wellbeing

September 2018

Mary Abboah-Offei (RN, MSc) and Professor Richard Harding (PhD, MSc, BSc)
Academic supervisor; King's College London

Signed



Professor Richard Harding
Herbert Dunhill Chair & Director of the Centre for Global Health Palliative Care
Florence Nightingale Faculty of Nursing, Midwifery & Palliative care
Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation
King's College London
Bessemer Road, London SE5 9PJ

Cicely Saunders International
Better care at the end of life

KING'S College LONDON
University of London

CERTIFICATE OF MENTORSHIP

This is to certify that

Dr Edwina Addo Opare-Lokko

Was a mentor on the following training course

Person-centred Communication and Holistic Needs Assessment of the Symptom Burden of People Living with HIV/AIDS in the Domains of Physical, Psychological, Social and Spiritual Wellbeing

September 2018

Mary Abboah-Offei (RN, MSc) and Professor Richard Harding (PhD, MSc, BSc)
Academic supervisor; King's College London

Signed

Professor Richard Harding
Herbert Dunhill Chair & Director of the Centre for Global Health Palliative Care
Florence Nightingale Faculty of Nursing, Midwifery & Palliative care
Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation
King's College London
Bessemer Road, London SE5 9PJ

Appendix T. Data collection tools for study Phase 3

Client ID: ---------- **Time: 0**

Pease tick box WHEN informed consent has been given by the patient (**Stored separately**): ☐

A novel community-based enhanced care intervention to improve person-centred outcomes for

Please answer all the questions in the order they appear in the booklet, don't worry if you make a mistake, just cross out and correct your answer. Although the questionnaire may look long, it should take not more than 40-60 minutes to complete.

The information you give us is strictly confidential.

There are no right or wrong answers. We are interested in your experience

Time	Date of interview	Form status	Date of next interview	Data entry 1	Data entry 2
0					

Form status
1=completed

If form is not completed, then give reason:
2= client refused
3= client left trial
4= unknown reason

Data entry
Checked by: (print name) ---------- Signature ----------

Client ID: ---------- **Time: 0**

Demographic questionnaire

The following questions are about you, your living conditions and your household

			ANSWER
D1	Gender	1=Male 2=Female	
D2	Age		
D3	Sexual orientation	1-Heterosexual 2-MSM 3-WSW 4-Bisexual	
D4	Has a partner	1=Yes 2=No	
D5	How many people are you financially responsible for?		
D6	How many children do you have?		
D7	What is the highest level of education you have attended?	0=No school 1 Four years of school or less 2=Primary 3=Secondary 4=Diploma 5=Degree or higher 6=Vocational school	
D8	What work do you do?	0-White Collar Worker 1-Petty bourgeoisie 2-Skilled Worker 3-Non-skilled Worker 4-Unemployed 5\-Retired	
D9	Date enrolled in HIV care		_ _/_ _/_ _
D10	Date of HIV diagnosis		_ _/_ _/_ _
D11	Date of ART initiation		_ _/_ _/_ _
D12	WHO clinical stage	1-Stage 1 2-Stage 2 3-Stage 3 4-Stage 4	
D13	CD4 count		
D14	Does your immediate family know about your HIV status?	1=Yes 2=No	

D15	What type of toilet do you use at home?	1=Private flush 2=Private VIP latrine 3=Private traditional pit (covered) 4=private traditional pit (uncovered) 5=public/shared 6=Bush/field/other	
D16	What is the main source of drinking water for your house?	0=Bottled 1=Sachet water 2=Piped inside house 3=Piped outside house 4=Protected well 5=Borehole 6=Rain water 7=Unprotected well 8=River/stream/pond 9=Tanker truck	
D17	What type of fuel does your household mainly use for cooking?	0=Electricity 1=LPG/natural gas 2= Paraffin/kerosene 3= Charcoal from wood 4= Firewood 5= Straw/shrubs/grass 6= No food cooked in household	
Does anyone in the household own a...?			
D18	Bicycle	1=Yes 2=No	
D19	Refrigerator	1=Yes 2=No	
D20	Television	1=Yes 2=No	
D21	Car	1=Yes 2=No	
D22	Radio	1=Yes 2=No	

Client ID: ---------- **Time: 0**

The APCA African POS

Question number	ASK THE PATIENT Questions 1-7	POSSIBLE RESPONSES	ANSWER
Q1	Please rate your pain (from 0 = no pain to 5 = worst/overwhelming pain) during the last 3 days	0 = No pain at all 1 = Slight pain 2 = Moderate pain 3 = Severe pain (interferes with activities of daily life) 4 = Very severe pain 5 = Overwhelming. The worst pain you can imagine	
Q2	Have any other symptoms (e.g. nausea, coughing or constipation) been affecting how you feel in the last 3 days?	0 = no, not at all 1 = slightly 2 = moderately 3 = severely 4 = very severely 5 = overwhelmingly	
Q3	Have you been feeling worried about your illness in the past 3 days?	0 = Not at all worried 1 = Worried very occasionally 2 = Worried some of time 3 = Worried a lot of the time 4 = Worried most of the time 5 = Worried all of the time	
Q4	Over the past 3 days, have you been able to share how you are feeling with your family or friends?	0 = Not at all 1 = Only once 2 = Occasionally 3 = Fairly frequently 4 = Often 5 = Yes, I've talked freely	
Q5	Over the past 3 days have you felt that life was worthwhile?	0 = Not at all 1 = Not very often 2 = Occasionally 3 = Some of the time 4 = Most of the time 5 = Yes, all the time	
Q6	Over the past 3 days, have you felt at peace?	0 = Not at all 1 = Not very often 2 = Occasionally 3 = Some of the time 4 = Most of the time 5 = Yes, all the time	
Q7	Have you had enough help and advice for your family to plan for the future?	0 = None 1 = Very little 2 = For a few things 3 = For several things 4 = For most things 5 = As much as wanted	

Client ID: ---------- **Time: 0**

The MOS-HIV

No.	QUESTION	POSSIBLE RESPONSES	ANSWER
I would like to ask you a few questions about your health.			
M1	In general, would you say your health is:	1=Excellent 2=Very good 3=Good 4=Fair 5=Poor	
M2	How much *bodily* pain have you generally had during the past thirty days?	1=None 2=Very mild 3=Mild 4=Moderate 5=Severe 6=Very severe	
M3	During the past thirty days, how much did pain interfere with your normal work, including both work outside the home and housework?	1=Not at all 2=A little bit 3=Moderately 4=Quite a bit 5=Extremely	
The following questions are about activities that a person might do during a typical day. Does your health now limit you in the following activities? And if so, how much?			
		1=Yes, limited a lot 2=Yes, limited a lot 3=No, not limited at all	
M4A	The kinds or amounts of vigorous activities you can do like digging, fetching water from a well, carrying a load, splitting firewood, running, lifting heavy objects or engaging in strenuous sports		
M4B	The kinds of moderate activities you can do like washing clothes, moving a jerrican of water or cleaning the house		
M4C	Walking up hill, climbing stairs		
M4D	Bending, lifting light objects or kneeling		

M4E	Walking a moderate distance, like the length of a football pitch or taking a village walk		
M4F	Feeding, dressing or bathing yourself or ability to use the latrine		
The following questions are about work. Does your health now restrict you in doing the following kinds of work?			
M5	Does your health keep you from working at a job, doing work around the house or attending school?	1=Yes 2=No	
M6	Have you been unable to do certain kinds or amounts of work, housework, schoolwork, because of your health?	1=Yes 2=No	

For each of the following questions, please tell me the answer that comes closest to the way you have been feeling.			
	(Interviewer must begin by reading this introductory question to the patient) ***How much of the time during the past 30 days:***	1=All of the time 2=Most of the time 3=A good bit of the time 4=Some of the time 5=A little of the time 6=None of the time	
M7	Has your health limited your social activities, like visiting with friends or family?		
M8A	Have you been a very nervous person?		
M8B	Have you felt calm and peaceful?		
M8C	Have you felt depressed?		
M8D	Have you been a happy person?		
M8E	Have you felt so depressed that nothing could cheer you up?		
M9A	Did you feel full of life and energy?		
M9B	Did you feel totally without energy?		
M9C	Did you feel tired?		
M9D	Did you have enough energy to do the things you wanted to do?		
M9E	Did you feel weighed down by your health problems?		
M9F	Were you discouraged by your health problems?		
M9G	Did you feel despair over your health problems?		

M9H	Were you afraid because of your health?		
M10A	Did you have difficulty reasoning and making decisions, for example, making plans or learning new things?		
M10B	Did you forget things that happened recently, for example, where you put things or when you had appointments?		
M10C	Did you have trouble keeping your attention on any activity for long?		
M10D	Did you have difficulty doing activities involving concentration and thinking?		

	Please tell me the answer that comes closest to describing whether the following statement is true or false for you.	1=Definitely true 2=Mostly true 3=Don't know 4=Mostly false 5=Definitely false	
M11A	You are somewhat ill		
M11B	You are as healthy as any other person you know		
M11C	Your health is excellent		
M11D	You have been feeling bad recently		
M12	How has the quality of your life been during the past thirty days? That is, how have things been going for you?	1=Very well, could hardly be better 2=Pretty good 3=Good and bad parts bout equal 4=Pretty bad 5=Very bad, could hardly be worse	
M13	How would you rate your physical health and emotional condition now compared to thirty days ago?	1=Much better 2=A little better 3=About the same 4=A little worse 5=Much worse	

Client ID: ---------- **Time: 0**

Picker Patient Experience questionnaire-15

		Possible responses	ANSWER
PEQ1	When you had important questions to ask a doctor, did you get answers that you could understand?	1= Yes, always 2= Yes, sometimes 3= No 4= I had no need to ask	
PEQ2	When you had important questions to ask a nurse, did you get answers that you could understand?	1= Yes, always 2= Yes, sometimes 3= No 4= I had no need to ask	
PEQ3	Sometimes in a hospital, one doctor or nurse will say one thing, and another will say something quite different. Did this happen to you?	1= Yes, often 2= Yes, sometimes 3= No	
PEQ4	If you had any anxieties or fears about your condition or treatment, did a doctor discuss them with you?	1=Yes, completely 2=Yes, to some extent 3=No 4=I didn't have any anxieties or fears	
PEQ5	Did doctors talk in front of you as if you weren't there?	1=Yes, often 2=Yes sometimes 3=No	
PEQ6	Did you want to be more involved in decisions made about your care and treatment?	1=Yes, definitely 2=Yes, to some extent 3=No	
PEQ7	Overall, did you feel you were treated with respect and dignity while you were in hospital?	1=Yes, always 2=Yes, sometimes 3=No	
PEQ8	If you had any anxieties or fears about your condition or treatment, did a nurse discuss them with you?	1=Yes, completely 2=Yes, to some extent 3=No 4=I didn't have any anxieties or fears	
PEQ9	Did you find someone on the hospital staff to talk to about your concerns?	1=Yes, definitely 2=Yes, to some extent 3=No 4=I had no concerns	
PEQ10	Were you ever in pain?	1=Yes 2=No If yes . . .	
PEQ11	Do you think the hospital staff did everything they could to help control your pain?	1=Yes, definitely 2=Yes, to some extent 3=No	

PEQ12	If your family or someone else close to you wanted to talk to a doctor, did they have enough opportunity to do so?	1=Yes, definitely 2=Yes, to some extent 3=No 4=No family or friends were involved 5=My family didn't want or need information 6=I didn't want my family or friends to talk to a doctor	
PEQ13	Did a member of staff explain the purpose of the medicines you were to take at home in a way you could understand?	1=Yes, completely 2=Yes, to some extent 3=No 4=I didn't need an explanation 5=I had no medicines—go to PP15	
PEQ14	Did a member of staff tell you about medication side effects to watch for when you went home?	1=Yes, completely 2=Yes, to some extent 3=No 4=I didn't need an explanation	
PEQ15	Did someone tell you about danger signals regarding your illness or treatment to watch for after you went home?	1=Yes, completely 2=Yes, to some extent 3=No	

Client ID: ---------- **Time: 0**

CARE Measure

Please mark the box like this **x** Please answer every statement.		
How good was the practitioner at ...?		
CA1	**Making you feel at ease** (introducing him/herself, explaining his/her position, being friendly and warm towards you, treating you with respect; not cold or abrupt)	Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐ Does not apply ☐
CA2	**Letting you tell your "story"** (giving you time to fully describe your condition in your own words; not interrupting, rushing or diverting you)	Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐ Does not apply ☐
CA3	**Really listening** (paying close attention to what you were saying; not looking at the notes or computer as you were talking)	Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐ Does not apply ☐
CA4	**Being interested in you as a whole person** (asking/knowing relevant details about your life, your situation; not treating you as "just a number")	Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐ Does not apply ☐
CA5	**Fully understanding your concerns** (communicating that he/she had accurately understood your concerns and anxieties; not overlooking or dismissing anything)	Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐ Does not apply ☐
CA6	**Showing care and compassion** (seeming genuinely concerned, connecting with you on a human level; not being indifferent or "detached")	Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐ Does not apply ☐

CA7	**Being positive** (having a positive approach and a positive attitude; being honest but not negative about your problems)	Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐ Does not apply ☐
CA8	**Explaining things clearly** (fully answering your questions; explaining clearly, giving you adequate information; not being vague)	Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐ Does not apply ☐
CA9	**Helping you to take control** (exploring with you what you can do to improve your health yourself; encouraging rather than "lecturing" you)	Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐ Does not apply ☐
CA10	**Making a plan of action with you** (discussing the options, involving you in decisions as much as you want to be involved; not ignoring your views)	Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐ Does not apply ☐
Comments: If you would like to add further comments on this consultation, please do so here.		

Client ID: ---------- **Time: 0**

Positive Outcomes: HIV PROM (version 1: 30.1.18)

1. What have been your **main problems and worries over the past 4 weeks** that you would like to be addressed?

a. ----------

b. ----------

c. ----------

2. In general, how would you rate your **health and wellbeing** over the past 4 weeks? *Please think about both physical and emotional wellbeing.*

Excellent	Good	Average	Poor	Very poor
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

3. Do you feel you have **enough information** to manage your HIV?

Enough Information, *The right amount for me*	Information received, *but hard to understand*	Information received, *but would like more*	Very little information, *and would like more*	No information received, *and would like information*
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

*The next few questions ask you more about your **physical** health and wellbeing.*

4. Over the past 4 weeks, how much have you been affected by **pain**? *This could include headache, joint pain, neuropathy (which might include pins and needles or burning pain) or any other pain in your body*

Not at all	Slightly	Moderately	Severely	Overwhelmingly
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

5. Over the past 4 weeks, how much have you been affected by **stomach or bowel problems**? *This could include sickness, diarrhoea, bloating, feeling sick or other stomach or bowel problems*

Not at all	Slightly	Moderately	Severely	Overwhelmingly
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

6. Over the past 4 weeks, how much have you been affected by problems with your **memory or concentration**?

Not at all ☐ 0	Slightly ☐ 1	Moderately ☐ 2	Severely ☐ 3	Overwhelmingly ☐ 4
7. Over the past 4 weeks, how much have you been affected by problems with your **sleep**?				
Not at all ☐ 0	Slightly ☐ 1	Moderately ☐ 2	Severely ☐ 3	Overwhelmingly ☐ 4
8. Over the past 4 weeks, have you been physically able to **carry out your usual activities**? *This could include washing, dressing, housework, work, study, leisure activities, socialising, as well as other things*				
Always ☐ 0	Most of the time ☐ 1	Sometimes ☐ 2	Occasionally ☐ 3	Not at all ☐ 4
*The next few questions ask you more about your **emotional** health and wellbeing.* 9. Over the past 4 weeks, have you been feeling **anxious or worried**?				
Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4
10. Over the past 4 weeks, have you been feeling **depressed or low in mood**?				
Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4
11. Over the past 4 weeks, have you felt worried about **telling someone about your HIV** status?				
Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4
12. Over the past 4 weeks, have you felt **good about yourself**?				
Always ☐ 0	Most of the time ☐ 1	Sometimes ☐ 2	Occasionally ☐ 3	Not at all ☐ 4
13. Over the past 4 weeks, have you felt **at peace**?				

Always ☐ 0	Most of the time ☐ 1	Sometimes ☐ 2	Occasionally ☐ 3	Not at all ☐ 4

*The next few questions ask you more about your **home and social life**.*

14. Over the past 4 weeks, have you been worried about your **safety** in your relationships? *This may include intimate relationships, or relationships with family, friends and other people around you.*

Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4

15. Over the past 4 weeks, have you or anyone close to you been worried about your **drug or alcohol** use?

Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4

16. Over the past 4 weeks have you been worried about **money**?

Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4

17. Over the past 4 weeks have you been worried about your **housing**?

Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4

18. Over the past 4 weeks have you been worried about your **immigration** status?

Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4

19. Over the past 4 weeks have you felt that you have had enough **support from people around you**? *This may include partners, friends, family, support groups and other networks.*

Always ☐ 0	Most of the time ☐ 1	Sometimes ☐ 2	Occasionally ☐ 3	Not at all ☐ 4

*These last few questions ask you more about **sex and intimate relationships**.*

20. Over the past 4 weeks, have you been worried about **sex or intimacy**?

Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4

21. Over the past 4 weeks, have you been worried about your **sexual health**?				
Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4
22. Over the past 4 weeks, have you been worried about **contraception?**				
Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4
23. Over the past 4 weeks, have you been worried about **starting a family or having a child**?				
Not at all ☐ 0	Occasionally ☐ 1	Sometimes ☐ 2	Most of the time ☐ 3	Always ☐ 4

Thank you for taking the time to answer these questions. Your answers are really important to us. They will help us to improve your HIV care by making sure that we can focus on the things that are most important to you.

Appendix U. PLWHA information for post-trial interview

INFORMATION SHEET

PLWHA POST-TRIAL QUALITATIVE INTERVIEWS

REC Reference Number: HR-17/18-7216

Phase II mixed methods feasibility cluster randomised controlled trial of a novel community-based enhanced care intervention to improve person-centred outcomes for people living with HIV/AIDS in Ghana

You will be given a copy of this information sheet

As people living with HIV/AIDS who has received standard care and enhanced care intervention, we would like to invite you to take part in one extra interview. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

We want to find out about your experience of receiving care in this study, and whether it has had any impact on your life, your relationships, your family or your own wellbeing. We will use this information to plan care for this clinic and others like it.

Why have I been chosen?

We are asking participants who have received care in the just ended study. We hope for 10 people in this clinic to agree to participate in this extra interview.

Do I have to take part?

No, you don't have to take part. You are free to withdraw at any time, and you don't have to give a reason. You will continue to receive treatment in this clinic either way.

What will happen if I take part?

You will be given this information to keep if you wish and asked to sign a consent form to show that you have agreed to participate. The researcher will ask you some questions about your experience of receiving care while you have been part of this study. This interview will take from 15minutes to 60minutes depending on how much you have to say. The interview will be recorded with your permission. None of the people providing you with care will hear the recording, just the research team. Your personal details (e.g. name and address) will not be given to anyone and your answers will be kept separately. We will use all responses to write up reports on how we think receiving care affects people and what is the most important part of this care. Nothing you say will be identified as coming from you. You will be asked to do this interview ONCE.

While taking part, you may be exposed to potential risks such as psychological, emotional or personal harm including disclosure of sensitive information. You can ask to take a break or stop the interview at any time. Everything you say will be completely private and confidential unless the interviewer thinks you or your family's safety is at risk. If this happens, they may have to tell someone in your care team who can ensure safety. This will not be done without discussing it with you first.

Are there any other effects of being in the study?

If you choose to participate, we will provide GHc12.50 (equivalent to £2) to pay for your transport to get to the clinic. When we finish the study, we will give copies of the final report to the clinic and arrange that you can have a copy if you want.

Will my taking part in this study be kept confidential?

All the information which we collect during the interview will be kept strictly confidential and anonymous. You will not be identified in any way, and your personal details (for example name and address will be kept separately from the information you give. We will NOT let anyone have any information that could identify you. Any information you give will NOT be kept with anything that could identify you (like your name or address). You may withdraw your data from the study at any time up until 31st of December 2018.

What happens to the result of the research study?

The findings from the study will go together with the findings from the feasibility trial you were also part of. This will help us understand if people receiving standard or enhanced care have better outcomes over time and what this experience is like. It will also help people to understand what is acceptable in

terms of care and why. We may also share the anonymous data with other researchers.

Who is organising the research?

This study is being organised by King's College London (UK). The Ghana Health Service Research Ethics Committee, Noguchi Memorial Institute for Medical Research Institutional Review Board and King's College London Research Ethics Committee have reviewed this study and approved it for your protection.

Who can I contact?

If you would like to talk to someone about the study, or get more information, or if you have experienced any harm as a result of this study, have any questions or require more information about this study, please contact:

Mary Abboah-Offei (Principal Investigator)

Cicely Saunders Institute of Palliative Care, Policy & Rehabilitation
Florence Nightingale Faculty of Nursing, Midwifery & Palliative care
King's College, London
Bessemer Road, Denmark Hill
London, SE5 9PJ
Telephone: +233544635508

Professor Richard Harding (1st Supervisor)

Cicely Saunders Institute of Palliative Care, Policy & Rehabilitation
Florence Nightingale Faculty of Nursing, Midwifery & Palliative care
King's College, London
Bessemer Road, Denmark Hill
London, SE5 9PJ
Telephone: +44 (0) 20 78485589

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

The Chair, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee Chair, rec@kcl.ac.uk

Local contacts:

1. Dr Naa Ashiley Vanderpuye,
   Chief Executive Officer - West Africa AIDS Foundation (WAAF)
   Plot 650, Ecomog Road Haatso,
   Ga East District, Greater Accra.

2. Dr Gloria A. Ansa MBChB MBA PhD (Leeds)
   Head of Public Health and Research
   University of Ghana Health Services,
   University of Ghana, Legon.

Thank you for reading this information sheet and for considering taking part in this research.

Appendix V. PLWHA consent form for post-trial interview

CONSENT FORM

POST-TRAIL INTERVIEWS WITH PLWHA

King's College Research Ethics Committee Ref: HR-17/18-7216

Phase III mixed methods feasibility cluster randomised controlled trial of a novel community-based Enhanced care to improve person-centred outcomes for people living with HIV/AIDS in Ghana

Please complete this form after you have read the Information Sheet and/ or listened to an explanation about the research.

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Please tick

1. I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be treated as strictly confidential and will be handled in accordance with the terms of the UK Data Protection Act 1998. ☐

2. I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data at any time up to January 2019. ☐

3. I agree that the research team or other researchers may use my data for future researchand understand that any such use of identifiable data would be reviewed and approved by a research ethics committee (In such cases, as with this project, data would not be identifiable in any report). ☐

Participant's Statement:

I _____ *(Participant's name)* agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project and understand what the research study involves.

Signed ---------- Date ---------- *Researcher's signature here*

Indicates witness to thumbprint

Researcher's Statement:

I _____ confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signed _____ Date_____

Appendix W. HCP information on post-trial interview

INFORMATION SHEET

HEALTHCARE PROFESSIONALS

POST-TRIAL QUALITATIVE INTERVIEWS

KING'S College LONDON

REC Reference Number: HR-17/18-7216

Phase III mixed methods feasibility cluster randomised controlled trial of a novel community-based Enhanced care to improve person-centred outcomes for people living with HIV/AIDS in Ghana

You will be given a copy of this information sheet

As a healthcare professional who deliver Enhanced care to people living with HIV/AIDS, we would like to invite you to take part in one interview. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

We want to find out about your experience of delivering care in this study, and whether it has had any impact on your practice, or your knowledge. We will use this information to refine the Enhanced care intervention.

Why have I been chosen?

We are asking healthcare professionals who delivered enhanced care in the just ended study. We hope for 5 healthcare professionals in this clinic to agree to participate in this interview.

Do I have to take part?

No, you don't have to take part. You are free to withdraw at any time, and you don't have to give a reason. You will continue to care in this clinic either way.

What will happen if I take part?

You will be given this information to keep if you wish and asked to sign a consent form to show that you have agreed to participate. The researcher will ask you some questions about your experience of delivering care while you have been part of this study. This interview will take from 30minutes to 60minutes depending on how much you have to say. The interview will be recorded with your permission, only the research team will listen to the interview recording. Your personal details (e.g. name and address) will not be given to anyone and your answers will be kept separately. We will use all responses to write up reports on: what it was like to deliver the Enhanced care and how it affected you as a professional.

Nothing you say will be identified as coming from you, and you will do this interview ONCE.

While taking part, there is a slight risk you may be asked about things that could make you feel anxious or embarrassed. You can ask to take a break or stop the interview at any time. Everything you say will be completely private and confidential unless the interviewer thinks you or other healthcare professional's safety is at risk. If this happens, they may have to tell someone in charge of the healthcare professionals in the clinic who can ensure safety. This will not be done without discussing it with you first.

Are there any other effects of being in the study?

If you choose to participate, there are expenses such as travelling cost to the clinic, these can be reimbursed.

When we finish the study, we will give copies of the final report to the clinic and arrange that you can have a copy if you want.

Will my taking part in this study be kept confidential?

All the information which we collect during the interview will be kept strictly confidential and anonymous. You will not be identified in any way, and your personal details (for example name and address) will be kept separately from the information you give. We will NOT let anyone have any information that could identify you. Any information you give will NOT be kept with anything that could identify you (like your name or address). You may withdraw your data from the study at any time up until January 2019.

What happens to the result of the research study?

The findings from this interview and that of the feasibility trial you were also part of delivering enhanced care will be merged together. The final result of the whole study will be shared with the two clinics which you can access a copy if you want. We will also feedback the findings to policy makers and to also disseminate the findings through peer review publications and research conferences.

Who is organising the research?

This study is being organised by King's College London (UK). The Ghana Health Service Research Ethics Committee, Noguchi Memorial Institute for Medical Research Institutional Review Board and King's College London Research Ethics Committee have reviewed this study and approved it for your protection.

Who can I contact?

If you would like to talk to someone about the study, or get more information, or if you have experienced any harm as a result of this study, have any questions or require more information about this study, please contact:

Mary Abboah-Offei (Principal Investigator)

Cicely Saunders Institute of Palliative Care, Policy & Rehabilitation
Florence Nightingale Faculty of Nursing, Midwifery & Palliative care
King's College, London
Bessemer Road, Denmark Hill
London, SE5 9PJ
Telephone: +233544635508

Professor Richard Harding (1st Supervisor)

Cicely Saunders Institute of Palliative Care, Policy & Rehabilitation
Florence Nightingale Faculty of Nursing, Midwifery & Palliative care
King's College, London
Bessemer Road, Denmark Hill
London, SE5 9PJ
Telephone: +44 (0) 20 78485589

Thank you for reading this information sheet and for considering taking part in this research.

Appendix X. Consent form for HCP post-trial interviews

CONSENT FORM

HEALTHCARE PROFESSIONAL'S POST-TRAIL INTERVIEWS

King's College Research Ethics Committee Ref: HR-17/18-7216

Phase III mixed methods feasibility cluster randomised controlled trial of a novel community-based Enhanced care to improve person-centred outcomes for people living with HIV/AIDS in Ghana

Please complete this form after you have read the Information Sheet and/ or listened to an explanation about the research.

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Please tick

1. I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be treated as strictly confidential and will be handled in accordance with the terms of the UK Data Protection Act 1998. ☐

2. I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data at any time up to January 2019. ☐

3. I agree that the research team or other researchers may use my data for future research and understand that any such use of identifiable data would be reviewed and approved by a research ethics committee (In ☐

such cases, as with this project, data would not be identifiable in any report).

4. I consent to my data being used in education for teaching and training. ☐

5. I consent to audio recording of my interview for research purposes. ☐

Participant's Statement:

I _____ *(Participant's name)* agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project and understand what the research study involves.

Signed ---------- Date ---------- *Researcher's signature here*

Indicates witness to thumbprint

Researcher's Statement:

I _____ confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signed _____ Date_____

Appendix Y. Post-trial interview guide for intervention arm

Post-trial qualitative data collection to assess PLWHA's experience and participation in the intervention.

Interview topic guide – Intervention

Greetings

Introduction

Before we met four months ago

Before we met four months ago, how would you describe your physical wellbeing? Talk to me about your physical health, pain and other symptoms. How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

Before we met four months ago, how would you describe your emotional and social wellbeing and or your state of mind? Talk to me about your emotional health, worries, depression, family relationships, community relations, sex and intimate relationships. How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

Before we met four months ago, how would you describe your spiritual wellbeing? Talk to me about your feelings of peace and how your health affected your ability to participate in an active spiritual life (attending church/ mosque/ diviner). How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

For the past three months you have been coming to the clinic

For the past three months you have been coming to the clinic how would you describe your experience of care? Have you noticed any change in any way?

Tell me more about your experience. How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

If change reported: What was important in this change taking place? Why/ how did it happen?

If no change reported: What do you think you need to be healthier or happier?

For you, what was the most important thing about the care you receive over the past three months – if anything, what helped you the most? Is there anything that could have been done differently which would have helped you?

How easy was it to answer all the questions from the researcher?

How did it make you feel, to answer all the questions from the researcher?

Thinking back, when I first invited you into the study, why did you say yes?

Now

Now, how would you describe your physical wellbeing? Talk to me about your physical health, pain and other symptoms. How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

Now, how would you describe your emotional and social wellbeing and or your state of mind? Talk to me about your emotional health, worries, depression, family relationships, community relations, sex and intimate relationships. How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

Now, how would you describe your spiritual wellbeing? Talk to me about your feelings of peace and how your health affected your ability to participate in an active spiritual life (attending church/ mosque/ diviner). How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

Now how would you describe the way HCP communication with you when come to the clinic?

What kind of questions are you asked?

What kinds of concerns are discussed?

What is important to you to discuss now?

Is it different in any way to the usual care you get at the clinic? If so, how? Are there anything that was better or worse?

Is there anything else you would like to add or tell me about your experiences of receiving care?

Appendix Z. Post-trial interview guide for HCP

Post-trial qualitative interview guide to assess healthcare professional's experience and delivery of the intervention.

Greetings

Introduction

Explanation of the purpose of interview, complete consent form and allocated participant ID

Briefly recount the feasibility cluster trial and the training healthcare professionals received in person-centred communication and holistic care assessment of physical, psychological, social and spiritual needs of PLWHA.

Intervention training manual

What are your views about the manual that was used in your training before the trial?

What did you find useful/ not useful? Was there anything new to you?

What are your views about the duration of the training (60minutes) per day?

What about the number of days the training was delivered?

The intervention

What are your views about the delivery of the intervention? Was it easy or complex? What is you understanding (comprehension high or low) of the intervention?

What is your understanding of person-centeredness/ holistic care as the basis for the intervention?

Tell me about your experience of delivering the enhanced care.

Would you say that you were able to deliver the enhanced care according to the training received? What was easy/ difficult? How would you suggest we improve the enhanced care model? What would you add or subtract from the enhanced care? Were there any challenges in delivering the enhanced care model?

Clients

What have you observed about your clients since you started delivering the enhanced care?

How did the client seem to feel about being more involved in their care decisions?

What would you say about the level of enthusiasm of clients wanting to contribute to their care?

How has this training affected you as a professional?

What things in particular will you do differently?

What are your views about each aspect of the training – physical, psychological, social spiritual care and person-centred communication?

Appendix AA. Post-trial interview guide for control arm

Post-trial qualitative data collection to assess PLWHA's experience and participation in the study.

Interview topic guide – Control clients

Greetings

Introduction

Before we met four months ago

Before we met four months ago, how would you describe your physical wellbeing? Talk to me about your physical health, pain and other symptoms. How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

Before we met four months ago, how would you describe your emotional and social wellbeing and or your state of mind? Talk to me about your emotional health, worries, depression, family relationships, community relations, sex and intimate relationships. How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

Before we met four months ago, how would you describe your spiritual wellbeing? Talk to me about your feelings of peace and how your health affected your ability to participate in an active spiritual life (attending church/ mosque/ diviner). How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

For the past three months you have been coming to the clinic

For the past three months you have been coming to the clinic, how would you describe your experience of care? Has it affected you, or changed you in any way?

Talk to me about your physical, emotional and or state of mind, and spiritual wellbeing, pain, symptoms, worries, depression, family relationships, community relations, sex and intimate relationships. How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

What would you say about the way HCP communicate with you?

If change reported: What was important in this change taking place? Why/ how did it happen?

If no change reported: What do you think you need to be healthier or happier?

For you, what was the most important thing about receiving care for the past three months – if anything, what helped you the most? Was there anything else you would like to add or tell me about your experiences over the past three months?

How easy was it to answer all the questions from the researcher?

How did it make you feel, to answer all the questions from the researcher?

Thinking back, when I first invited you into say yes?

Now

Now, how would you describe your physical wellbeing? Talk to me about your physical health, pain and other symptoms. How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

Now, how would you describe your emotional and social wellbeing and or your state of mind? Talk to me about your emotional health, worries, depression, family relationships, community relations, sex and intimate relationships. How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why was that?

Now, how would you describe your spiritual wellbeing? Talk to me about your feelings of peace and how your health affected your ability to participate in an active spiritual life (attending church/ mosque/ diviner). How did this affect your ability to work, day to day activities and your ability to function to acceptable level? Why is that?

Now when you come to the clinic how will you describe your communication with HCP? Now are you able to discuss your problems and concerns freely with HCP?

Prompts and probes

Amplification: Could you tell me a little more about that? Could you give me an example of that? When you say that, what gave you that impression What exactly was it that you liked? How did you respond when? What did you feel when? Why do you think this is important? What effect did that have on you? Did that help in any way? **Explanatory:** What makes you say that? What was it about this that made you feel/ do/ decide to etc.	**Clarification:** How was that helpful/ unhelpful/ difficult? Could you explain what you mean by...? Before you said …. But you also say …. [highlighting contradiction]. What are the main feelings you're left with? **In-depth iterative probing:** This may sound like an obvious question, but…… I want to make sure I've really understood you. What was it exactly that you meant by……?

Appendix BB. Published qualitative paper for thesis Phase 2

Taylor & Francis

AIDS Care

Psychological and Socio-medical Aspects of AIDS/HIV

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How can we achieve person-centred care for people living with HIV/AIDS? A qualitative interview study with healthcare professionals and patients in Ghana

Mary Abboah-Offei, Katherine Bristowe, Jonathan Koffman, Naa Ashiley Vanderpuye-Donton, Gloria Ansa, Melanie Abas, Irene Higginson & Richard Harding

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How can we achieve person-centred care for people living with HIV/AIDS? A qualitative interview study with healthcare professionals and patients in Ghana

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ABSTRACT

Although person-centred care (PCC) has been identified as a means to achieve the 90-90-90 targets, limited research has considered PCC in low- or middle-income settings. We aimed to explore what constitutes PCC from the perspectives of PLWHA and healthcare professionals (HCP) in Ghana. We conducted 39 semi-structured qualitative interviews with PLWHA and HCP in two community clinics in Ghana, West Africa. Interviews were analysed deductively using thematic analysis, and sampling continued until thematic saturation was achieved. Twenty-four PLWHA (median age 42.5, 50% female) and 15 HCP (median age 34, 53% female) were interviewed. Three interconnected themes emerged across PLWHA and HCP: (1) care structures not built around the person, (2) priority outcomes and components of PCC and (3) re-engineering HIV care to be more person-centred. A conceptual model showing the overlap between PLWHA and HCP's perspectives of PCC and a framework to inform PCC delivery have been developed from these findings. Our data revealed that PLWHA want PCC to improve care outcomes, well-being and quality of life. Further testing of this model is required to inform PCC delivery for PLWHA in low- and middle-income countries.

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HIV/AIDS; holistic care; person-centred care; Ghana; community-based care

Introduction

People living with HIV/AIDS (PLWHA) frequently experience highly distressing physical, psychological, social and spiritual concerns (Harding et al., 2010; Harding, Selman, et al., 2012; Harding et al., 2013; Harding et al., 2014), which negatively impact upon their quality of life (Harding, Clucas, et al., 2012). Moreover, these symptoms and concerns influence engagement and retention in care and treatment adherence (Gonzalez, Batchelder, Psaros, & Safren, 2011; Nachega et al., 2013). Greater attention has been paid to viral suppression at the expense of broader psychological, social and spiritual concerns that persist despite treatment advances (Fontaine, Larue, & Lassaunière, 1999; Harding et al., 2010). To address these issues, holistic assessment and person-centred care (PCC) are required.

Person-centeredness is a key to quality healthcare (Epstein, Fiscella, Lesser, & Stange, 2010) and is represented in the statement "nothing about me, without me" (Delbanco et al., 2001). It is defined as care "dedicated to the promotion of health as a state of physical, mental, sociocultural, and spiritual well-being, as well as to the reduction of disease, and founded on mutual respect for the dignity and responsibility of each individual person" (Mezzich, Snaedal, van Weel, & Heath, 2009). PCC has been recognised as a means to achieve the 90-90-90 targets set by the World Health Organisation (WHO) (WHO, 2016). However, PCC is a Western-originated concept that is claimed to be potentially applicable universally despite it not being tested in Africa (Jeroen De Man et al., 2016; Setlhare, Couper, & Wright, 2014).

The WHO's "Global Strategy on Integrated People-Centred Health Services" recommends that people should be provided with opportunities, skills and resources to make informed and effective decisions about their own health (WHO, 2015). Evidence from high-income countries for conditions other than HIV has shown that a shift to PCC enhances collaboration between healthcare providers and patients and adherence to treatment plans (Roumie et al., 2011; Thompson & McCabe, 2012), improves health outcomes and increases patient satisfaction (Bertakis & Azari, 2011; Ekman et al., 2012). Moreover, the adoption of person-

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centred approaches in primary healthcare has resulted in significant benefits for patients, enabling better health management by being informed and supported (Delaney, 2018). This will be increasingly important as PLWHA age and live with complex comorbidity and clinical uncertainty.

We aimed to understand the conceptual meaning of PCC for PLWHA in sub-Saharan Africa and to determine what specific components of care constitute PCC from the perspectives of PLWHA and healthcare professionals (HCPs).

Materials and Methods

Study design

This is a qualitative study using semi-structured interviews, reported in accordance with the consolidated criteria for reporting qualitative research (COREQ) (Tong, Sainsbury, & Craig, 2007), to enhance trustworthiness and transparency of findings.

Setting

This study was conducted in two community clinics in Accra, Ghana, from September 2017 to December 2017. The participating clinics provided services including ART, adherence counselling and care for key populations (including men who have sex with men (MSM) and sex workers).

Sampling and recruitment

The inclusion criterion for PLWHA was adults aged at least 20 years (WHO, 2013), with an HIV diagnosis and known to the treating clinic for at least 6 months and had cognitive ability to consent according to their referring clinician. The inclusion criterion for HCP was to have been providing care for PLWHA for at least 6 months. A purposive sampling frame was applied to recruit a heterogenous sample with respect to gender, sexual orientation and socio-economic status for PLWHA.

Ethical approvals

This study was approved by King's College London Research Ethics Committee Reference no. LRS-16/17-4507; the Ghana Health Service Ethics Review Committee Reference no. GHS-ERC16/06/17 and Noguchi Memorial Institute for Medical Research – Institutional Review Board Reference no. NMIMR-IRB004/17-18. All participants provided written informed consent prior to data collection.

Data collection

Face-to-face and semi-structured interviews were conducted by one researcher (MA-O) in participants' respective clinics. An initial semi-structured topic guide was developed and written in English, then forward and backward translated into Twi. This guide was piloted and amended to improve coherence and questioning. MA-O is fluent in both languages and gave participants the option of participating in English, Twi or a combination of the two. The interview questions addressed participants' perspectives of their illness, access to care, involvement in care decisions, symptoms and concerns and their preferences for care. Interviews with PLWHA and HCP included questions about PCC: "How involved are you in your care? What role do you play in your care? How do you tell staff what matters to you?" For HCP, we explored: "What do you know about PCC? What in your view constitute PCC for PLWHA?".

To increase the validity of the data collected, MA-O summarised the discussions at the end of each interview to allow the participant to clarify any misconceptions or add additional information. Recruitment continued until data saturation was achieved (Saunders et al., 2018). Interviews were audio recorded, transcribed verbatim and pseudonymised to ensure confidentiality. Translated transcripts from Twi to English were checked with the audio recordings for consistency. A distress protocol was developed and enacted for one patient who became distressed during interviews.

Data analysis

Thematic analysis (Braun & Clarke, 2006) was used to deductively analyse both PLWHA and HCP interviews informed by the WHO's framework on integrated people-centred health services (WHO, 2015). MA-O read transcripts for familiarisation with the data and coded line by line to generate initial coding framework. LC and SE independently reviewed four randomly selected transcripts and performed line-by-line coding using the initial framework generated by MA-O to develop a mutually agreed coding framework. The same researchers (MA-O, LC and SE) met to reconcile and agree on a final coding framework through discussion. This unified coding framework was applied to both PLWHA and HCP data sets. Themes and subthemes were labelled using a definition of their meaning, expounded to specify their content, to enable internal consistency for each discrete code, and exemplified

using extracts from the data. QSR NVivo 11 was used to assist data management and analysis. MA-O further refined and revised codes throughout the analysis, which was reviewed with KB and RH until all data were coded. Findings have been used to inform a conceptual model of PCC and a framework to inform PCC delivery (Figures 1 and 2, respectively).

Results

Participant characteristics

Twenty-four PLWHA and 15 HCP were recruited for interviews. Median interview duration was 50 minutes (range 45 to 73 minutes). Sample characteristics are reported in Table 1.

Three interconnected themes emerged across PLWHA and HCP data: (1) care structures not built around the person, (2) priority outcomes and components of PCC and (3) re-engineering HIV care to be more person-centred. Illustrative quotes from (1) and (2) are from both; however, the quotes from (3) are just from HCPs. The themes and sub-themes are described in turn below, and illustrative quotes are provided in Table 2.

Table 1. Participants' characteristics $N = 39$.

PLWHA ($n = 24$)	N (%) Total
Gender:	
Male	12 (50%)
Female	12 (50%)
Sexuality:	
Men who have sex with men	7 (29%)
Heterosexual	16 (67%)
Women who have sex with women	1 (4%)
Religion:	
Christian	13 (54%)
Muslim	4 (17%)
Traditional believer	7 (29%)
Relationship status:	
Single	9 (38%)
In relationship	15 (62%)
Age:	
Median (range)	42.5 (20–65)
Clinical:	
Median years since diagnosis	5.5 (6months–18years)
PLWHA with comorbidities (diabetes, hypertension, arthritis, migraine, hepatitis)	16 (67%)
HCP ($n = 15$)	
Median Age	34 (24–56)
Profession:	
Doctor	2 (13%)
Nurse	5 (33%)
Pharmacist	2 (13%)
Counsellor	2 (13%)
Social worker	1 (7%)
Human resource manager	1 (7%)
Laboratory technician	1 (7%)
Healthcare assistant	1 (7%)
Gender:	
Male	7 (47%)
Female	8 (53%)
Median years delivering HIV care	2 (6months–14years)

Care structures not built around the person

Participants discussed multifaceted concerns including discrimination, stigma and care structures and processes that hinder access to HIV care services.

Discrimination and stigma. HIV-related stigma and discrimination remain a major barrier to PLWHA accessing care services. Discrimination from HCP prevented PLWHA from accessing services at both private and public health facilities (quote 1). Participants also described perceptions and experiences of stigma related to an HIV diagnosis. Stigma emerged as self-stigma, as well as perpetrated by family and community. Expectations and experiences of stigma were a major barrier to accessing care services (quote 2).

Fear of status disclosure. Fear of recognition as someone living with HIV also acted as a barrier to accessing care. For example, signposts placed in front of clinics describing services provided at the clinic (including HIV and related services) was identified as a barrier for PLWHA to accessing the clinic (quote 3). These barriers were recognised by HCP who emphasised effects of these signposts in front of the clinic (quote 4).

Dual burden of disclosure of HIV status and sexual orientation. For MSM, the dual burden of disclosure of HIV and homosexuality were a major concern since same sex relationships have not been legalised in Ghana. Participants felt they could not disclose their sexuality to family, friends or work colleagues. Unable to disclose to their families, some MSM described challenges when family members found out about their HIV or relationship status themselves, causing high levels of distress (quote 5).

Poverty, community care and waiting times. Furthermore, many participants described poverty as their biggest barrier to accessing appropriate care. Although ART is dispensed free of charge, PLWHA have financial difficulties that prevented them from accessing services or adhering to treatments (quote 6). For some, this was compounded by the decision to travel long distances to access care far from home to avoid being identified by people in their community (quote 7). The importance of care services being located in the community and flexible to the needs of PLWHA was recognised. Most participants described wanting their care available in community and with walk in services to enable easy access to care when needed (quote 8). However,

Table 2. Subthemes and illustrative quotations from participants.

Sub-themes	Source	Representative quote
Discrimination	PLWHA	(1) "Due to mistreatment from health workers some of us stopped attending such clinics until we find a place where we are treated as human beings. Another issue is when you attend the clinic and you are a man with the complains of diarrhoea, even without asking you what or how did the diarrhoea started, staff just assumed that you are gay they will just leave you there without any medical assistance, is as if they wish you die at that moment with your symptoms. This is very demoralising you know most importantly when you soil yourself with the diarrhoea, no health worker is even willing to change your soiled clothes or linen, this really gives you a low spirit and also you begin to have self-stigma." MSM, age 25.
Stigma	HCP	(2) "Stigma is also another major barrier that prevent PLWHA from being free in themselves and to utilise the services available for them. Sometimes when you are being nice to the clients, they don't understand why you should be nice to them because they have always been stigmatised even at health facilities" female age 46.
Fear of status disclosure	PLWHA	(3) "I think a good care should be delivered in the community where it is near to the community members to access however, there should not be any signpost indicating that the clinic cares for HIV/AIDS clients, otherwise people will start to know our status and we may have to abandon those community clinics for other ones that are not closer to us" MSM, age 26.
	HCP	(4) "We had enough signpost around the community however, some members of the community realising what we do, begun to label any client that comes to the clinic, some even went to the extent of discriminating against some of our staff because they cared for PLWHA" male, age 32.
Dual burden of disclosure of HIV status and sexual orientation	PLWHA	(5) "My family has not accepted me with my HIV status, my dad doesn't talk to me, he only talks to me when he thinks I should conform to his rules then he will address me with my status; my house is like mummy and daddy makes the rules and you are only to conform but I am very stubborn, so I don't usually obey what mum and dad says so it looks like I am the odd one out. My mum keeps reminding me of how she is at risk of getting HIV from me, dad also tries to say things that will make me feel guilty like he will say things like I am a disappointment to the family and telling me to give birth because he thinks am going to die soon" MSM, age 20.
Poverty	HCP	(6) "The main discussion has been around finances because even though the ARTs is free, there are other supplementary drugs or lab investigations that clients need to do. Generally, clients think that because the HIV/AIDS treatment is free, everything else that comes with it should be free; others may also come, pay for all their treatment and when it is time to go home, they tell you they don't have money for transport. So the clinic has to find a way to pay for their transport or if these clients live close by, then the clinic vehicle will take them home" female, age 32.
	PLWHA	(7) "The main thing that will prevent me from attending my appointments will be when I don't have money to take car to the clinic because I don't have a straight car from my house to the clinic, I had to chatter a taxi that will bring me closer to the town before I take a commercial vehicle from town to the clinic. And I don't want people to see me going to the clinic and be asking questions" male, age 43.
Community care	PLWHA	(8) "I think that the care in the community is good because it is less formal and you don't need an appointment to go to the clinic" female, age 52.
Waiting times	PLWHA	(9) "I expect that the moment I arrive in the clinic, they will just see me, give my medications then I go because we MSM we know ourselves and I am a bit popular too so when I am delayed in the clinic, other MSM will come to the clinic and identify me the same way I will identify them, and they will go and talk about the fact that they saw me in the clinic and the rest of us will like to know why I was at the clinic" MSM age 27.
Care communication	HCP	(10) "So now the concern is what can we do to keep our clients in care? And because clients take their pill every day when you go back to talk to them that please take your pills, they feel derailed, they want to see other innovations that are interesting to them like, pill boxes, colourful text messages. I noticed that most of my clients don't want to hear you asked them have you taken your drugs, so I have started using things like pebbles, so like have you taken your pebbles, just things that will not remind them of what they are taking. Most of them are getting used to it that I get messages from them like 'my pebbles have finished can I come and get some more?" male, age 33.
Continuity of care	PLWHA	(11) "Staff usually speak to me about my ART and how to take my medication regularly so that my viral load will go down. But they don't ask me about my home and my life outside HIV" male, age 43.
	PLWHA	(12) "It's also important to me that the same staff is maintained at the clinic because I hardly open up to people about my issues and concerns. The last time I came I met a doctor who was nice to me so I started sharing my issues and concerns with her but today when I came to the clinic, the doctor that saw me is a new doctor as a result, I couldn't discuss my issues and concerns with her because she is new to me and I have to try and develop a relationship with this doctor before I can open up to this doctor about my issues which will really take a while to happen" MSM age 25.
Physical, psychological, social and spiritual well-being	PLWHA	(13) "I have headaches, pain, fatigue and weakness in my body which sometimes prevent me from going to work. The pain can be unbearable to the extent that I am not able to get out of my room." female, Age 42.
	PLWHA	(14) "I worry most of the time about how I got HIV, I feel if it hadn't been for this HIV, I would have achieved greater heights in life. I feel that being HIV positive has really drawn me back in life, this makes me sad and am filled with regrets." female, Age 43.
	PLWHA	(15) "My husband does not treat me well since he got to know my HIV status. He won't look after the children and he will insult me sometimes in front of the children making me feel that I am not a human being. I don't have any money because when I got HIV and news of it went round, it made people stopped buying from me which has rendered me jobless because people feel they will get HIV if they buy from me or even talk with me." female, Age 35.
	PLWHA	

(*Continued*)

Table 2. Continued.

Sub-themes	Source	Representative quote
		(16) "May be God is even the one who punished me with the HIV because when I had a girlfriend I was not diagnosed of HIV until I started dating a man. I don't really understand my life anymore, I am always praying for God's forgiveness." MSM, Age 25.
Family and intimate relationship	PLWHA	(17) "What I want to ask staff, is about me and my wife, we want to have another child but we are not sure if we can have a child whiles on treatment or if it is even possible to have children at all because we have been advised to have protected sex so we are not sure if we can have unprotected sex let alone have a baby. I have been thinking about this for a while now but have not had the courage to ask the doctor or any other staff" male, age 41.
	PLWHA	(18) "I just wanted to have unprotected sex with this other woman so that perhaps she might get pregnant for me, then I can have a child of my own because after my wife had the still birth I wasn't sure if she will be able to carry another pregnancy for me so that is why I decided to date this other woman to see if I stand the chance of having another child even if it is outside my marriage who cares" male, age 43.
Involvement in care and personalised care	PLWHA	(19) "I am not involved in my care and staff don't ask me my opinion about my care. I am not sure if I have a role to play in my care if I do, then staff have not told me about the role I need to play in my care. Staff don't ask me what matters to me and I don't think I have a say in my care." male, Age 36.
	PLWHA	(20) "Staff should have other conversations with us regarding other aspects of our life apart from HIV. Staff should also ask us about what is most important to us so that we can tell them about it. Staff should not assume they know all things, they should also treat us like human beings because our HIV status is not written in our faces to scare them of, we are human beings just like staff" male, age 61.
	HCP	(21) "Like dealing with PLWHA is very different because when you are caring for PLWHA you are psychosocially and spiritually involved with their issues that are related or intertwine, so you see that you are sitting there trying to help someone's child enrol in school, or you are talking to somebody's husband who is discriminating against her. So you are involved in so many levels, and that is what is interesting about HIV care, because strictly PLWHA mainly come here for their counselling and medication refill but what we need to have at the back of our mind is we are not focusing on just HIV, we are dealing with a whole human being" female, age 46.
What is person-centred care?	HCP	(22) "When we talk about person-centred care it should be having tailored care or targeted care because people are different. For me person-centred care is having differentiated models that will suit their needs. So we call it targeted care because a married man walking to the clinic who is HIV positive will have different needs to a young man who is HIV positive, and it will also be different with MSM who walk into the clinic." male, age 33.
Achieving person-centred care	HCP	(23) "Yes, it is possible to practice person-centred care but only when we are trained to understand what it means to be person-centred and what benefit it will be to PLWHA. Because what I observe is that one doctor mostly consults on Saturdays due to her busy schedules on week days; but because of her approach to caring, most of the PLWHA prefer to come for the Saturday clinic" male, age 32.
	HCP	(24) "I think the only thing we need to do is what we call integration of services and resource ourselves to do more capacity building and training for health workers to understand what person-centred care means so that they are fit to handle some of problems and concerns of PLWHA. Another thing too is that we need to do a lot of research because for us in Ghana we need research to tell us what influences what we do and because we don't have the research most of the time we do things the old way" male, age 33.
	HCP	(25) "I think we need both financial and human resources because before you can have a discussion with a client with psychological issues to come out smiling you need more than 30minutes with that client. And as you are having such conversation with clients you will realised that there are financial issues that you may need to help the client with, like paying their transportation etc. I find it difficult to ask my client 'what is really bothering you?' And I am not happy that when clients share such problems, I am not in a position to help them so I will rather not ask" male, age 25.
	HCP	(26) "Or we can also identify and train staff to be able to handle such things, because we have at least 5 nurses we can identify at least 2 nurses who can be trained to support our clients especially MSM with these psychological issues, then we know we have such team in place. We should also focus our conversation on the client like trying to find out what is happening in the person's life before touching on HIV-related issues at the tail end of the conversation" female, age 38.

extended periods of waiting in the clinic, where their status may be disclosed, was an additional barrier to accessing care for PLWHA (quote 9).

Care communication and continuity of care. HCP also described the importance of careful communication to retain PLWHA in care and ensure adherence to their ART. Due to the stigma associated with ART, HCP identified creative and innovative approaches of discussing and reminding PLWHA about medication (quote 10). Communication between PLWHA and HCP was further described in relation to topics of discussion. PLWHA described interactions with HCP being mainly focussed on their HIV and ART, not broader psychosocial domains (quote 11). They also described frustration due to lack of continuity of care, with staff changes undermining relationship building and discouraging disclosure of concerns (quote 12).

Priority outcomes and components of PCC

When asked what mattered most to them, PLWHA described outcomes across broad domains of need

including symptoms, living a "normal life", marriage, having children and being employed. This strongly contrasts those outcomes identified by HCP, which were achieving high CD4 counts and lower viral loads; adherence to treatment and having a normal kidney and liver function tests results.

Physical, psychological, social and spiritual well-being. PLWHA described the need for support for symptoms and concerns in four domains: physical, psychological, social and spiritual. Participants described a range of physical symptoms that affect their activities of daily living, well-being and quality of life (quote 13). Living with HIV also impacted significantly on the psychological well-being of PLWHA. In particular, they described worries for their future, fears regarding disclosure of their HIV status and regrets and anger for contracting HIV and how it has affected their life to date (quote 14). This psychological morbidity was compounded by the social, economic and physical environment for PLWHA. They expressed concerns about lack of family support, unemployment and lack of money to support self and family (quote 15). The overwhelming impact of HIV across physical, psychological and social domains resulted in PLWHA questioning the meaning of their existence. They described spiritual distress, feeling the need to be at peace with God and the importance of spiritual support to engender hope and bring meaning to their lives (quote 16).

Family and intimate relationship. Concerns for PLWHA also extended to intimate relationships. They described a need for PCC that also addressed these relational needs, in particular information about starting sexual relationships with a HIV-negative person and having children (quote 17). PLWHA also expressed uncertainties around fertility and their ability to have children while living with HIV, particularly in the cases where one partner is HIV negative. They described a lack of information on these resulting in them questioning the future of their relationships (quote 18).

Involvement in care and personalised care. In addition to the inadequate information, PLWHA also felt they were not actively involved in making decisions about their own care, as involvement in care was rare and they felt unable to have a say in their care (quote 19). PLWHA described a need for care that addresses what is important to them, involving them meaningfully in care decisions, and delivered by professionals who are interested in them as a person and not only their HIV (quote 20).

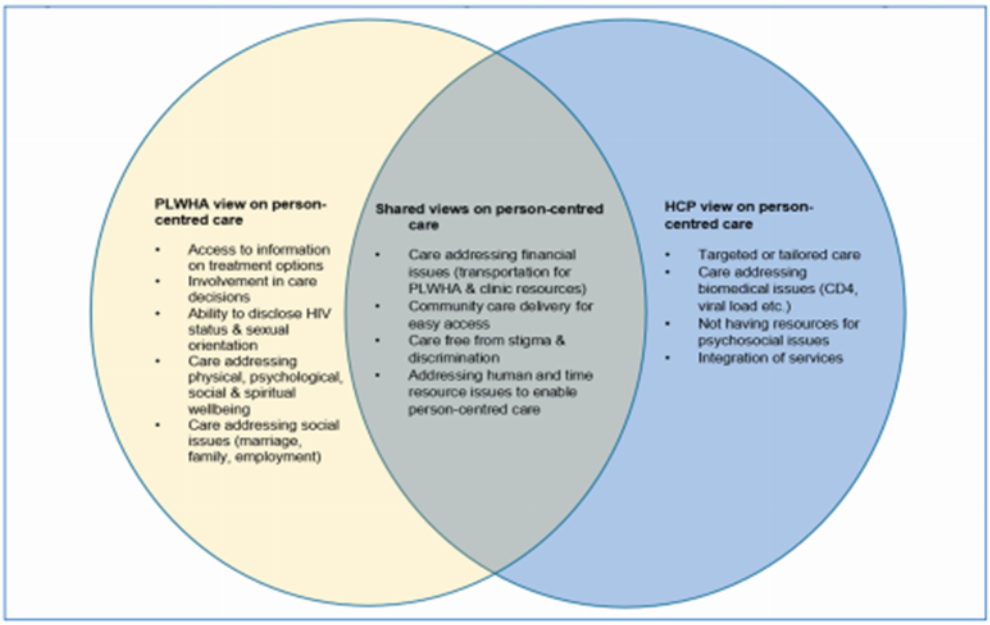

Figure 1. A conceptual model of person-centred care from the perspectives of HCP and PLWHA in community care in Ghana.

What is person-centred care?. Some HCP did recognise the construct of PCC, describing the importance of considering the psychosocial and spiritual needs of the individual to see beyond the HIV diagnosis to the whole person (quote 21). However, HCPs described PCC differently, as "tailored care" and "targeted care" (quote 22). Although HCP target care toward the individual, decisions around what that care should include, and care needs are led by the HCP's view of what is important not by the expressed priorities of PLWHA.

While some views regarding PCC were common across the PLWHA and HCP interviews, others were specific to one or other of the participant groups. Both PLWHA and HCP in Ghana described PCC as care that is delivered in the community, free from stigma and discrimination, which addresses financial, human and time resource issues. We present a conceptual model demonstrating the differences and commonalities of views expressed on PCC in Figure 1.

Re-engineering HIV care to be more person-centred Achieving person-centred care. HCP identified a need for training to understand what PCC means and how it could benefit PLWHA (quote 23). Alongside training for professionals, HCPs identified the need for support in coordinating and integrating adjunct services to address the holistic care needs of PLWHA and more evidence from research undertaken in Ghana to inform service design and delivery (quote 24). HCP also outlined challenges related to resources required to deliver PCC, including financial, human and time resources (quote 25). They also identified challenges specifically in relation to providing care for key populations. One solution proposed was to train selected staff in providing care to these highly stigmatised communities and to support their specific needs (quote 26).

Changes to services and infrastructure required to enable PCC have been modelled in Figure 2.

Figure 2 provides potential steps required to implement PCC in community HIV care settings, building on the WHO's five strategic goals for integrated people-centred health services. This could be achieved through a system-wide approach by carefully working to understand the needs of PLWHA, alongside training and mentoring HCP on PCC delivery, effective communication, holistic assessment and management of symptoms and concerns. Together these would foster relationships building, collaborative decision-making, resulting in desired outcomes.

Discussion

This study provides novel insight into what constitutes PCC for PLWHA beyond the original western-oriented concept.

PLWHA understand PCC as care that involves them in their care decisions, which is concerned about the whole person and not only viral suppression and

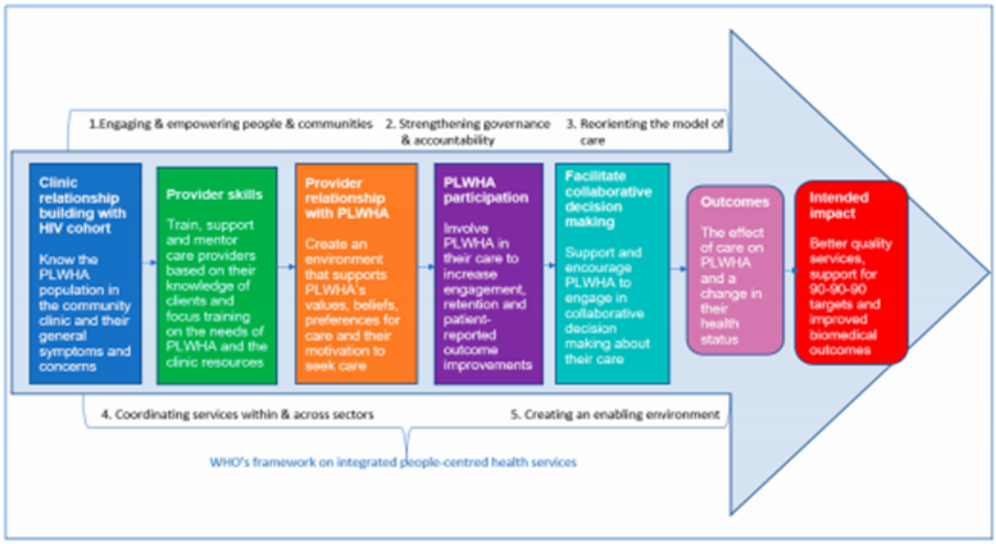

Figure 2. Framework to inform person-centred care delivery.

addresses what matters to them (Figure 1). PLWHA also view PCC as addressing broader social issues: living a normal life like anyone else, getting married and having children and being employed. In contrast, HCP described PCC as "tailored care" and "targeted care"; however, this was focussed on their own perspectives as to what is important, rather than that of the PLWHA. This was borne out in HCP data, which identified priority outcomes as biomedical (CD4, viral loads). This contrasts starkly with the PLWHA data, which described social outcomes (living a normal life, getting married and having children). These differing priorities resulted in care that was not person-centred, as HCP expressed uncertainty about how PCC could be practiced, and a need for training.

A major challenge faced by PLWHA in low- and middle-income countries is the stigma associated with HIV disease, which also has impact on service utilisation and physical health (Bennett, Traub, Mace, Juarascio, & O'Hayer, 2016; Herek, Saha, & Burack, 2013). It has been argued that PLWHA are ensnared in a sequence where psychological problems are compounded by stigma (Miller et al., 2016). These and other issues relating to diversity, ethnicity, gender, sexual orientation, religion and socio-economic status could be addressed using a person-centred approach (Epstein et al., 2010) in ensuring that patients have equal access to vital care service (Groene, 2011). A recent study demonstrates the potential to increase PLWHAs' resistance to stigma using PCC delivery (Lowther et al., 2018).

PCC is associated with improved clinical outcomes and cost effectiveness (Bezold, 2005; Olsson, Hansson, Ekman, & Karlsson, 2009; Soman & Larson, 2009), as it allows services to target scare resources at a greatest need, which could also prevent further health service use due to unmet needs. "Person-centred care made simple", a UK Health Foundation report presented evidence about cost savings and a decrease in healthcare services utilisation (Health Foundation, 2014), which implies that when individuals are better informed, they could choose different treatments that are less expensive when supported to manage their own care more effectively (Coulter & Collins, 2011; Lm, 2012). This is clearly highly relevant to HIV care services in Africa.

Strengths and limitations

This study provides, for the first time, an understanding of the meaning of PCC in HIV population in Ghana, from the perspectives of key stakeholders. A maximum variation sample was achieved, and we oversampled MSM (29%), which is notable considering that same sex relationships are not legalised in Ghana. This study had some limitations: we were unable to recruit heterosexual participants between the age group 20–29 years; hence, their specific views and experiences may not have been represented. Furthermore, it is possible that some subtleties derived from the data interpretations may have been lost due to translated transcripts from Twi to English, as there is not always a direct translation from Twi to English.

Clinical and research implications

To implement and achieve PCC in community settings, we recommend:

(1) Relationship building between stakeholders through effective communication and acknowledgement of patients as experts in their own healthcare through partnerships that allow for sensitivity to patient's values, needs and preferences for care.
(2) Ongoing education and training for providers on PCC delivery, with a specific focus on holistic patient assessment, management of symptoms and concerns, collaborative care planning and delivery.
(3) Increased understanding of patient's perspective for PCC to inform the content of HCP training.
(4) Future research should test this framework for PCC and validate it across a larger and more diverse sample of PLWHA.

Conclusion

We present a framework for PCC delivery informed by the experiences and perspectives of PLWHA and their HCPs. Further testing of this framework can serve to inform national policies and plans for HIV service implementation and delivery. While this framework can provide guidance for implementing PCC, there is still a need for health systems to be responsive to their specific contexts and to identify priority areas to encourage innovation for PCC. Policies and plans for strengthening health systems to better serve people with chronic conditions such as HIV/AIDS should be aligned with principles of PCC to strengthen patients' knowledge and skills to participate in and benefit from their care.

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Disclosure statement

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Appendix CC. Published Feasibility cRCT paper for thesis Phase 3

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Phase II mixed methods' feasibility cluster randomised controlled trial of a novel community-based enhanced care intervention to improve person-centred outcomes for people living with HIV in Ghana

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Phase II mixed methods' feasibility cluster randomised controlled trial of a novel community-based enhanced care intervention to improve person-centred outcomes for people living with HIV in Ghana

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ABSTRACT

Person-centred care (PCC) for people living with HIV (PLWH) is a global goal for WHO and the UNAIDS strategy. We aimed to develop a novel person-centred intervention for community providers, test the feasibility of participant recruitment and retention, intervention delivery and to establish acceptability. Findings from qualitative interviews with PLWH and healthcare professionals were mapped onto a PCC theory in an expert intervention development workshop. A parallel feasibility cluster randomised controlled trial (cRCT) was conducted. We randomly assigned clusters (1:1) either to intervention or to standard care. The primary outcome was trial recruitment and retention. We screened 83 PLWH, enrolled 60 with 30 allocated to each arm. Recruitment and retention rates were 87% and 97%, respectively. Potential effect size achieved at final timepoint: a measure of person-centred outcomes [0.7 (95% CI 0.17–1.23) $p < 0.001$]; MOSHIV [0.7 (95% CI 0.17–1.23) $p < 0.001$]; Patient Experience Questionnaire [0.8 (95% CI 0.27–1.31) $p < 0.001$]; CARE Measure [1.0 (95% CI 0.45–1.55) $p < 0.001$], POSITIVE OUTCOMES [0.7 (95% CI 0.17–1.23) $p < 0.001$]. Post-trial interviews revealed general acceptability of the intervention. The results confirm the feasibility and justify a definitive cRCT of the enhanced care intervention to improve person-centred outcomes for PLWH.

Trial registration number ISRCTN13630241.

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Person-centred care; holistic assessment; HIV/AIDS; ghana; community-based care

Introduction

UNAIDS estimates that during 2017, approximately 36.9 million people were living with HIV, 21.7 million accessed antiretroviral therapy (ART), 1.8 million people were newly infected and 940, 000 people died from AIDS-related disease (UNAIDS, 2018/2019). In the same year, 75% of people living with HIV knew their status; 79% of people who knew their status were accessing treatment; 81% of people accessing treatment were virally suppressed (UNAIDS, 2018/2019), from the UNAIDS 90–90–90 treatment targets set. Among the critical areas of action outlined for achieving the 90–90–90 targets was to keep individuals alive and healthy through the delivery of "person-centred and holistic care" (WHO, 2016).

Person-centred care (PCC) is care "dedicated to the promotion of health as a state of physical, mental, socio-cultural, and spiritual well-being, as well as to the reduction of disease, and is founded on mutual respect for the dignity and responsibility of each individual person" (Mezzich et al., 2009). Selman et al. noted the importance of holistic care and assessment, which addresses physical, psychological, social and spiritual well-being in HIV care, highlighting that spiritual well-being is often omitted (Selman et al., 2013). The person-centred approach is a core principle for quality healthcare which enables providers to deliver high-quality care that is responsive to the needs of individuals (Wolfe, 2001).

People living with HIV (PLWH) perceive that care delivered to them does not often address broader psychological, social and spiritual concerns which persist despite treatment advances (Fontaine et al., 1999; Harding, Lampe, et al., 2010). This highlights the need for PCC, which values and recognises individuality (Lutz & Bowers, 2000) and approaches care delivery as a partnership between the patient and the provider (Robinson et al., 2008; Wolf et al., 2017). A randomised control trial in an HIV population in Kenya reported that the use of

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person-centred assessment and care delivered by trained healthcare professionals (HCP) had a positive effect on self-reported mental health-related quality of life [0.61 (95% CI 0.13–1.10) $p = 0.01$] and psychosocial well-being [0.69 (95% CI 0.26–1.120) $p = 0.002$]. Also, evidence suggests that using a person-centred approach to care mostly improves outcomes (Olsson et al., 2013). These include supporting individuals to learn more about their conditions, resulting in their engagement in health discussions, and training health professionals to facilitate care that empowers individuals to participate (Lewin et al., 2001; McMillan et al., 2013).

Despite the benefits of PCC, the concept has not been well explored in Africa; as it is believed to be a western-originated concept that is claimed to be universally applicable (Jeroen De Man et al., 2016; Setlhare et al., 2014). We aimed to develop a community-based enhanced care intervention (CECI) to improve person-centred outcomes for PLWH, and to test the feasibility of a cluster randomised controlled trial (cRCT) in terms of participant recruitment and retention, intervention delivery and acceptability, and estimate of potential effect to determine if a future definitive trial is warranted.

Methods

Design

As recommended by the Medical Research Counsel's (MRC) guidance for developing and evaluating complex interventions (Craig et al., 2008), we conducted a parallel, mixed methods design (Creswell & Clark, 2007), comprising quantitative outcome data collection in a feasibility cRCT and post-trial exit interviews. This is reported in accordance with the CONSORT extension to randomised pilot and feasibility trials (Eldridge et al., 2016). This design was chosen to inform a future definitive cRCT.

Inclusion criteria

PLWH were included if they were adults from age 20 (WHO, 2013); and had a positive diagnosis of HIV/AIDS known to the patient for at least 6 months to ensure they have the experience of care to reflect on; and had cognitive ability to consent according to the consulting clinician.

Setting

This study was conducted in two community clinics in Ghana: West African AIDS Foundation and the Public Health Unit of Legon Hospital, both in Accra, Ghana.

Recruitment

PLWH were initially approached about the study by their HCP and those who expressed interest in the study had their details passed on to the researcher (MA-O), who then approached these PLWH, and screened them against the inclusion criteria. Eligible PLWH were taken through the information and consent process, and those who consented were recruited.

Sample size

In order to determine the feasibility of recruitment to inform a future definitive trial, a sample size of 30 has been recommended to estimate a parameter such as a standard deviation for the calculation of future sample size (Browne, 1995). Therefore, a total of 60 participants were recruited across the two clusters in a ratio of 1:1.

Randomisation

After baseline data collection, the two clinics were randomised to "Intervention" or "Control" by independent off-site computerised randomisation.

Intervention (CECI)

Participants in the clinic allocated to the intervention arm received clinical care from HCP who received three-session training programme on PCC and communication; use of holistic assessment tool to assess symptoms and concerns in the domains of physical, psychological, social and spiritual well-being; collaborative care planning and delivery, and twice-weekly ongoing clinical supervision and mentorship. Findings from an initial qualitative interview with PLWH and HCP were mapped onto the PCC theory in an intervention expert development workshop (see Figure 1 for steps used in developing the intervention).

Control

Participants in the clinic allocated to the control arm received standard HIV care delivered by the clinic. HCP who have had no exposure to the CECI intervention provided this care consisting of six-monthly clinical assessments once ART has been established, and brief appointments for ART refill, among others.

Blinding

Due to the nature of this study, participants and treating clinicians could not be blinded to the assignment to intervention or control arm.

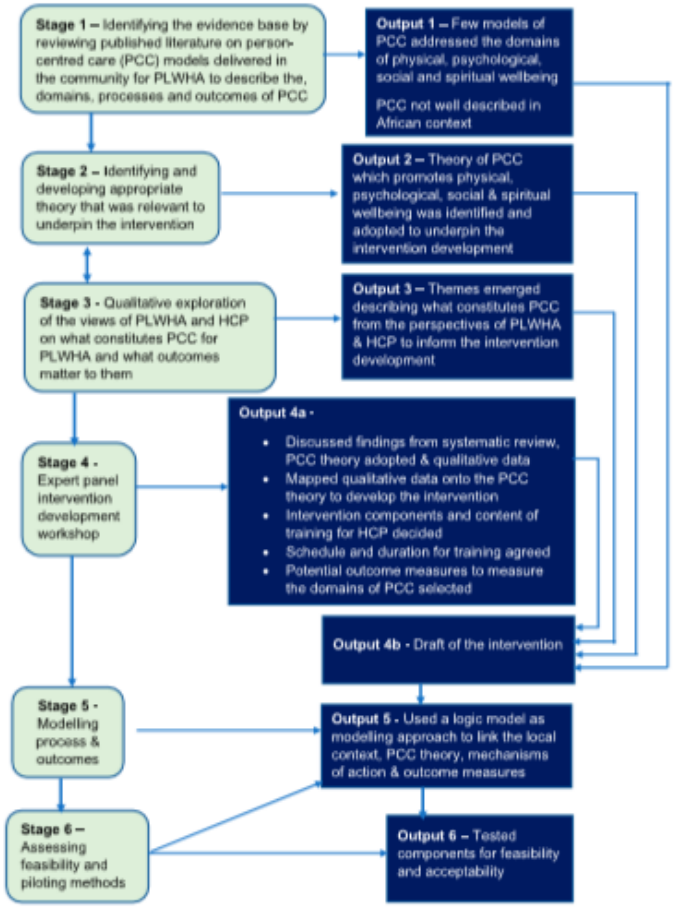

Figure 1. Process of CECI development.

Baseline and follow-up measures

Outcome measures were mapped onto the goals of the CECI. The selected outcome measures focused on physical, psychological symptoms, spiritual, practical and emotional concerns and psychosocial needs measured using APOS, which consists of 10 items using a scoring method appropriate for a range of literacy skills with a scoring range 0–5, with some items needing recoding (Harding, Selman, et al., 2010). Role function, pain, physical functioning, cognitive functioning, social functioning, general health perception, mental health and health distress vitality were measured with the Medical Outcome Scale-HIV (MOS-HIV), which consists of 35 items (Mast et al., 2004). In addition to the items measured by APOS and MOS-HIV, sleep disturbance, drug/alcohol use, immigration status, and sex and intimate relationship were measured using Positive Outcomes, which is a brief person-centred measure consisting of 23 items of which the first item is an open question about PLWH's "main problems and worries over the past 4 weeks" (Bristowe et al., 2019). CARE Measure, a 10-item person-centred validated process measure was used to measure the amount of empathy that a patient feels they have received during a consultation (Mercer et al., 2004).

Patient Experience Questionnaire (PEQ), an 18-item self-reported measure, was used to measure patient experience along the domains of communication; emotions; short-term outcomes; barriers; and relations with staff (Steine et al., 2001). All these measures have been validated; for MOS-HIV and CARE Measure, high scores indicate better outcome, for the rest of the measures low scores indicate better outcomes.

Participants completed outcome measures face to face with the researcher (time range 30–63 min) at baseline (including demographics such as age, sexual orientation, relationship status, level of education, employment status, and CD4 among others), six to eight weeks before they attended CECI delivery, then month 1, month 2 and month 3 completion after CECI delivery. These time intervals were selected to enable identification of the optimal time for follow-up measure collection in a future definitive trial. Participants requiring support with outcome measure completion were used as a feasibility marker.

Feasibility cRCT outcomes

The primary outcomes for this feasibility cluster RCT were

(1) Recruitment rate
(2) Retention rate

The secondary outcomes included:

(1) Fidelity of design, intervention training and delivery,
(2) Intervention acceptability,
(3) Estimate of potential effect size.

Feasibility and acceptability

Avery et al.'s (2017) recommended specifying progression criteria for feasibility studies; therefore, a priori criteria specified for this study were

- Recruitment of 30 PLWH within 8 weeks for each cluster,
- Retention of 80% of the total sample at month 3 follow-up,
- Establishment of intervention acceptability and fidelity.

Data collection and time points

Data were collected monthly over three months after baseline assessment and HCP training on CECI delivery. Participants had the freedom to choose whether to conduct the interviews in Twi or English or both languages. MA-O contacted participants who failed to attend an appointment to remind them. A two-week window was allowed after missing a scheduled appointment, after which non-attendance was recorded as missing. Data collection was recorded at month 1 (T1), month 2 (T2), and month 3 (T3). At each time point, PLWH received either the CECI or SHC before completing the outcome and process measures. Data were collected in the counselling room or a private space within the clinic when the counselling room was in use.

Two weeks after the delivery of CECI, PLWH participants and HCP were interviewed as a sample on their experience of the intervention training, delivery and experience of participating in the trial.

Data analysis

The feasibility of the study methodology was examined using the quantitative data on recruitment, retention, follow-up outcome measure response rates and missing follow-up outcome measure data. Quantitative analysis was by descriptive statistics (means and SD, or n and %), using SPSS v 25, estimated at 95% confidence interval and standardised effect size calculation using Cohen's d where $d = 0.2$ is a small effect size, $d = 0.5$ is medium and $d = 0.8$ is large (Cohen, 2013) (using the difference between two means) The statistical analysis was completed by MA-O and supported by RH. The analytical framework developed by Bugge (Bugge et al., 2013) was applied to systematically categorise and explore issues in feasibility studies based on the 14 potential methodological issues identified by Shanyinde and colleagues (Shanyinde et al., 2011) (see Table 1).

Intervention feasibility and acceptability were explored with PLWH and HCP through post-trial exit interviews conducted by MA-O with a purposive sample size of 20 PLWH (sampled by age, participation in the trial and treatment arm) and 7 HCP (sampled by participation in CECI training and delivery). Post-trial qualitative interview data were analysed using the thematic analysis recommended by Braun and Clarke (Braun & Clarke, 2006). These interviews were audio-recorded, transcribed verbatim, anonymised and imported into NVivo 12 for data management and analysis. MA-O was the primary coder. SE, LB and LC independently coded a subset of transcripts to inform the coding framework, consensus on coding framework key themes was reached through discussion, ensuring a robust analysis (Meyrick, 2006).

Ethics

This study was approved by the King's College London Research Ethics Committee (LRS-17/18-7216), the Ghana Health Service Ethics Review Committee (GHS-

Table 1. Summary of findings against the 14 methodological issues in feasibility.

Methodological issues	Findings	Evidence
Did the feasibility study allow a sample size calculation for the main trial?	Yes	$N = 60$ (Browne, 1995)
What factors influenced eligibility and what proportion of those approached were eligible?	Adults age 20 yrs, had been diagnosed for more than 6 months and had cognitive ability to consent	83% of those approached were eligible
Was recruitment successful?	Yes	A total of 60 participants were recruited between the two sites within 6 weeks
Did eligible participants consent?	Yes	60 recruited out of 69 eligible, consent rate of 87%
Were participants successfully randomised and did randomisation yield equality in groups?	Yes, and randomisation yielded equality in groups	Two clusters were randomised to "Intervention" ($n = 30$) and "Control" ($n = 30$)
Were blinding procedures adequate?	No	Participants blinded; HCP could not be blinded, and researcher was not blinded
Did participants adhere to the intervention?	Yes	60 PLWH recruited, 30 received CECI HCP had good adherence to CECI
Was the intervention acceptable to the participants?	Acceptability was explored in qualitative interviews	PLWH and HCP found CECI acceptable and feasible
Was it possible to calculate intervention costs and duration?	No	Intervention costs – No Duration – Yes
Were outcome assessments completed?	Yes	APOS – 93%, 98%, 97% at T1, T2 & T3 MOS-HIV– 93%, 98%, 97% at T1, T2 & T3 PEQ – 93%, 98%, 97% at T1, T2 & T3 CARE Measure– 93%, 98%, 97% at T1, T2 & T3 Positive Outcomes – 93%, 98%, 97% at T1, T2 & T3
Were outcomes measured those that were the most appropriate outcomes?	Outcomes were consistent with the theory underpinning CECI	See summary of outcome data in table 4
Was retention to the study good?	Retention was good	Response rates: Time point one (28/30) – 93% Time point two (30/30) – 98% Time point three (28/30) – 97%
Were the logistics of running a multicentre trial assessed?	Recruitment was rapid at both sites. The presence of the researcher at each site positively influenced participant identification and recruitment	Site 1: 30 PLWH Site 2: 30 PLWH
Did all components of the protocol work together?	Components worked well together	There were no difficulties identified in the various processes and the researcher's ability to implement them. Participants once recruited were readily identified.

ERC) GHS-ERC008/06/18 and the Noguchi Memorial Institute for Medical Research Institutional Review Board (NMIMR-IRB) NMIMR-IRB004/17-18 amend. 2018.

Results

Recruitment and baseline data collection ran from July 2018 to August 2018 (see Table 2 for comparison of the two cluster sites). Final post-trial exit interviews were completed in January 2019.

Recruitment and retention

Eighty-three potential PLWH participants were screened, 69 PLWH were approached, 60 were recruited and 30 received at least two sessions of CECI. The proportion of PLWH approached who consented (conversion to consent) was 87% (Bugge et al., 2013). Figure 2 shows the CONSORT flow diagram of recruited participants (Eldridge et al., 2016). A recruitment and retention rate of 87% and 97% were achieved within 6 weeks and at the end of final time point, respectively.

Table 3 shows the baseline characteristics of participants. There was no significant difference between the intervention and control arms with regard to age, gender sexual orientation, or CD4 count. The mean age of participants in the intervention arm was slightly younger than the control arm (36.6 vs 38.9) and the intervention had more female (18 vs 13) and heterosexual participants (25 vs 19).

CECI delivery

PLWH attended three intervention appointments scheduled monthly for over 3 months (see Figure 3 for steps taken to deliver CECI). All visits entailed using a holistic assessment tool to assess physical, psychological, social and spiritual symptoms and concerns, after which a personalised care planning was undertaken based on symptom and concerns assessment, treatment and care goals. This plan is updated and revised by HCP throughout the course of the intervention delivery to provide holistic person-centred care. HCP in the intervention arm also had twice-weekly supervision and mentorship meetings with the researcher to discuss and review the intervention delivery, challenges and any complex cases that they may have encountered.

Table 2. Characteristics of the two cluster sites.

Variables	Control	Intervention
Cohort of PLWHA	500	750
Average PLWHA seen per day	10–30	15–40
Accept National Health Insurance Scheme	Yes	Yes
Clinic days	Wednesdays and Fridays	Monday to Saturday
Walk in services	Yes	Yes
Services provided	General practice including, Tuberculosis, Hepatitis, Prevention of Mother to Child Transmission, ART, pre-counselling and testing and Sexually Transmitted Infections services	General practice including, Tuberculosis, Hepatitis, Prevention of Mother to Child Transmission, ART, pre-counselling and testing and Sexually Transmitted Infections services
No. of doctors	4	2
No of nurses	4	4
Social workers	2	1
Laboratory services	Yes	Yes
Counsellors	2	2
Models of hope (PLWHA trained to provide counselling)	2	1
Healthcare assistance	2	2
Staff from Ghana AIDS Commission	1	2
Support key populations (Lesbians, MSM, bisexual, sex workers and drug users)	Yes	Yes
Pastoral services	Occasionally	Occasionally
Psychological care	Occasionally	Occasionally

CECI compliance/adherence

CECI compliance was high, only four participants from the intervention arm missed one session and none missed more than one. Outcome measure compliance was also high; 11.7% ($n = 4$ for the intervention arm and $n = 3$ for the control arm) of data were lost for month 1, 2 and 3 for all measures, which was predominantly due to participants missing their appointments. Each CECI session lasted 30–60 min. All 30 participants randomised to the intervention arm received CECI with each participant receiving at least two sessions, and no one dropped out during CECI delivery. A total of 3 CECI sessions were completed one session each per month. At 3-month trial endpoint, only two participants (2 sets of outcome measures) were missing as they failed to attend their appointment despite sending them reminders.

Baseline and follow-up data assessment

Of 30 participants who received CECI, two individual participants missed their first and last appointments; however, none withdrew from the trial and no adverse events were recorded during the trial, see Table 4 for follow-up rates. The potential effect sizes estimated at 95% confidence interval (CI) at final timepoint were: APOS [0.7 (95% CI 0.17–1.23) $p < 0.001$]; MOS-HIV [0.7 (95% CI 0.17–1.23) $p < 0.001$]; Patient Experience Questionnaire [0.8 (95% CI 0.27–1.31) $p < 0.001$]; CARE Measure [1.0 (95% CI 0.45–1.55) $p < 0.001$], POSITIVE OUTCOMES [0.7 (95% CI 0.17–1.23) $p < 0.001$]. See Table 5 for details of change scores estimated for all time points post-CECI delivery, these analyses are useful for explorative and descriptive purposes only.

Post-trial qualitative interview findings

Twenty PLWH ($n = 10$ from intervention and $n = 10$ from control arms) and 7 HCP were interviewed. Interviews ranged from 30 to 46 min in length. Two main themes emerged across PLWH and HCP data: (i) intervention experience and acceptability and (ii) benefits of participating in the study. The themes and sub-themes are described in turn below, and illustrative quotes to exemplify the sub-themes are presented in Table 6.

(i) Intervention experience and acceptability

Participants in the intervention arm revealed the acceptability and perceived benefits of the intervention, including PLWH being partners in care delivery and the intervention fostering open communication among PLWH and HCP.

Care as partnership: PLWH described a novel experience of care that focused on them as individuals and considered them as partners in their own care (quote 1, Table 6). This was demonstrated by HCP's interest in the problems experienced by PLWH alongside their HIV disease, as well as involving them in planning their care (quote 2).

Intervention changing HCP's perspectives: HCP, on the other hand, described the intervention as opening their eyes to the broader challenges faced by PLWH, which they felt unprepared to address (quote 3). As a result of using the holistic approach within the intervention, which also involved PLWH in their care decisions, HCP noted the positive impact this had on their clients (quote 4). This has contributed to reflective practice among HCP who expressed fulfillment and satisfaction at the results of their collaborative care practice with PLWH (quote 5).

Openness in care communication: This collaboration between HCP and PLWH in PCC delivery has fostered open communication where PLWH feel able to discuss their symptoms and concerns freely with HCP for appropriate management (quote 6).

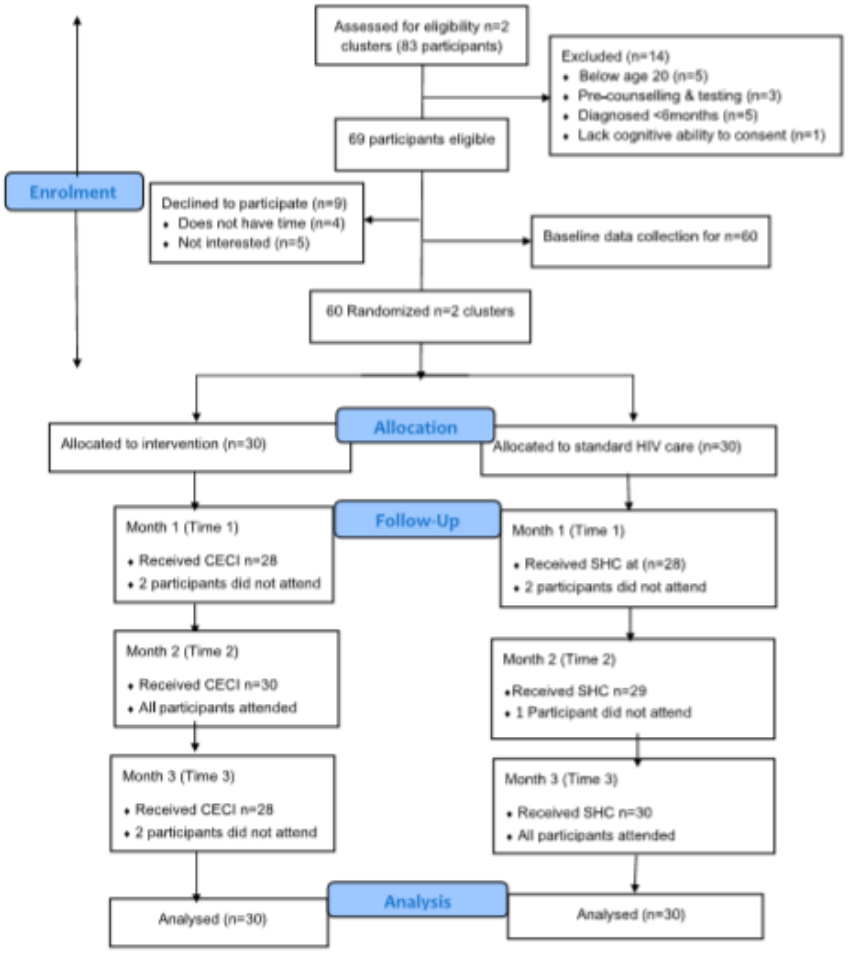

Figure 2. CONSORT flow diagram.

Time spent in delivering care: However, despite the intervention benefits described, HCP expressed concerns about spending more time in delivering the intervention, and the impact upon the service (quote 7).

(ii) Benefits of participating in the study

For some participants, taking part in the study, having someone to talk, and the additional focus of appointment on their well-being as well as their, was a source of motivation for attending clinical appointments (quote 8).

Discussion

This study demonstrates that a person-centred intervention (CECI) delivered in the community to improve person-centred outcomes for PLWH is feasible and acceptable to PLWH and HCP. The methods used were successful as demonstrated by the high recruitment and

Table 3. Baseline characteristics of participants.

Participant characteristics at baseline						
	Control arm (*n* = 30)		Intervention arm (*n* = 30)		Total (*n* = 60)	
	N (%)	Mean (SD)	*N* (%)	Mean (SD)	*N* (%)	Mean (SD)
Age (years)		38.9 (11.66)		36.6 (10.23)		37.75 (10.94)
Gender: female	13 (43.3)		18 (60.0)		31 (51.7)	
Sexual orientation						
Heterosexual	19 (63.3)		25 (83.3)		44 (73.3)	
MSM	5 (16.7)		3 (10.0)		8 (13.3)	
WSW	1 (3.3)		–		1 (1.7)	
Bisexual	3 (10.0)		2 (6.7)		5 (8.3)	
Missing	2 (6.7)				2 (3.3)	
Has a partner (yes)	19 (63.3)		20 (66.7)		39 (65.0)	
Number of children		1.37 (1.47)		2.07 (1.44)		1.72 (1.49)
Number of financial dependants		1.24 (1.27)		2.83 (2.48)		2.05 (2.12)
Education						
No school					3 (5.0)	
Primary	1 (3.3)		2 (6.7)		6 (10.0)	
Secondary	2 (6.7)		4 (13.3)		22 (36.7)	
Diploma	7 (23.3)		15 (50.0)		17 (28.3)	
≥Degree	13 (43.3)		4 (13.3)		12 (20.0)	
	7 (23.3)		5 (16.7)			
Employment status						
White Collar Worker	4 (13.3)		3 (10.0)		7 (11.7)	
Shop keepers (informal shops in the form of kiosk used for petty trading)	15 (50.0)		20 (66.7)		35 (58.3)	
Skilled Worker	1 (3.3)		–		1 (1.7)	
Non-skilled Worker	2 (6.7)		7 (23.3)		9 (15.0)	
Unemployed	7 (23.3)	363.59 (137.31)	–	366.91 (145.49)	7 (11.7)	365.12 (139.68)
Missing	1 (3.3)				1 (91.7)	
CD4 count (cells/mm^3)						
WHO clinical stage						
Stage 1	4 (13.3)		–		4 (6.7)	
Stage 2	21 (70.0)		24 (80.0)		45 (75.0)	
Stage 3	4 (13.3)		4 (13.3)		8 (13.3)	
Stage 4	1 (3.3)		–		1 (1.7)	
Missing			2 (6.7)		2 (3.3)	

retention rates with little missing data, good compliance and protocol adherence demonstrating the feasibility and acceptability of the CECI. The CECI intervention was well integrated into the existing clinic practices where HCP were able to assess and manage the symptoms and concerns of PLWH holistically. Study implementation strategies were effective including HCP support with recruitment, the randomisation conducted by an independent statistician, HCP training on CECI and its delivery and the twice-weekly fidelity checking, mentorship and supervision meetings held with the researcher to address any concerns, challenges and to assess how HCP were fairing delivering CECI. These findings will inform a future definitive cluster RCT.

Recruitment was successful at both clinics as there were high eligibility and acceptance rates to participate in the study. When designing this feasibility study, we purposely made use of a cluster design to minimise the potential of study contamination (Fayers et al., 2002; Torgerson, 2001), associated with the movement of both HCP and PLWH acquainted with the CECI to the control arm, which may influence the care received by PLWH in the control arm. This study design was feasible in the HIV population. Among the experiences created by CECI for PLWHA were that they felt listened to, informed, respected, and involved in their care decisions and their wishes honoured as well as experience holistic assessment of their symptoms and concerns. HCP recognised the value of CECI because it gave them the opportunity to holistically and systematically assess symptoms and concerns. However, HCP also expressed concerns that although the holistic assessment tool was able to capture more symptoms and concerns, it also lengthened clinical reviews as it has taken them at least 30 min to see one PLWH, and at most 60 min for others; coupled with the completion of care plans. Therefore, in a future definitive cluster trial, there will need to be careful consideration of cost implications. As this is a feasibility trial, it is not in the scope of feasibility trials to do a full cost analysis. We, therefore, recommend that the time spent by health workers on this intervention should be investigated further in a definitive trial in order to find appropriate solutions. And we also hypothesise that it is potentially cost-saving due to the prevention of problems and health service use, reducing admission and crisis management and retention in care.

None of the participants found the completion of the outcome measures burdensome although some

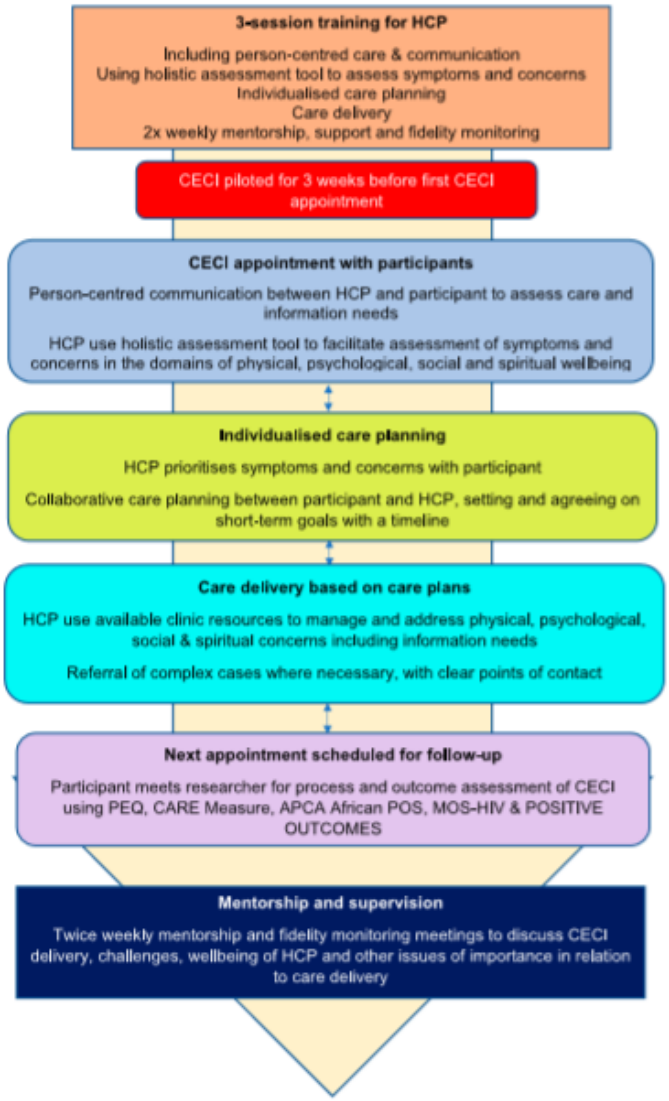

Figure 3. Sequential steps of CECI delivery.

participants required some assistance in the form of reading the questions and the responses out for them to provide their preferred response to each question. The APCA POS, MOS-HIV, PEQ, CARE Measure and Positive Outcomes were observed as being feasible with no missing data for retained participants. The measures were acceptable, but further consideration is needed to define a primary outcome for a definitive trial.

Table 4. Follow-up rates.

Time points	Outcome measures CECI $n = 30$ n (%)	Outcome measures SHC $n = 30$ n (%)	Whole sample $n = 60$ n (%)
Month 1 (T1)	28(93%)	28(93%)	56(93%)
Month 2 (T2)	30(100%)	29(97%)	59(98%)
Month 3 (T3)	28(93%)	30(100%)	58(97%)

The study has some strengths including it was a clinical feasibility trial of a complex community-based enhanced care intervention, recruiting 60 PLWH within 6 weeks of our targeted 8 weeks recruitment timeline, at a rate of 87%. Furthermore, data were collected from these participants at multiple time points; and the knowledge gained from this study contributes to progressing how research can be conducted with PLWH in community settings. PLWH also viewed their involvement in the study positively and many were grateful for the opportunity to share their experiences.

Limitations

This study only recruited from two community clinics, of which only one clinic received CECI to improve person-centred outcomes for PLWH. Therefore, findings do not represent the wider PLWH population. The researcher (MA-O) was involved in all study stages including study design, implementation and subsequent analysis data for which it was difficult for the researcher to be blinded. As a result, this may have introduced bias, specifically in the assessment of the feasibility and acceptability of CECI training and delivery. However, CECI training and delivery at the cluster level where a whole team was trained to deliver the CECI, is the strength of this intervention in enhancing the existing care delivered to PLWH rather than creating new ones and can easily be integrated into routine care.

Conclusion

This study provides vital evidence to inform future research evaluating complex interventions for PLWH in community settings. The feasibility testing demonstrates that the CECI is feasible and acceptable for PLWH and HCP. PLWH were excited about being involved in making decisions about their own care and their symptoms and concerns being assessed and addressed holistically using PCC. Training on CECI was well received by HCP who felt equipped with skills to carry out a holistic assessment and to practise PCC. Recruitment and retention targets have been met, including a priori feasibility criteria. The study also conforms to the recommendation that clear feasibility objectives are set in advance to inform whether the study

Table 5. Outcome measure data: Outcome data for completed (fully or partially) have been presented $n = 60$.

	Control (SHC)							Intervention (CECI)							Potential Effect size [95% CI] of the intervention at:
Measures	Baseline Mean (SD) or n (%)	Time 1 Mean (SD) or n (%)	Change score Mean (SD)	Time 2 Mean (SD) or n (%)	Change score Mean (SD)	Time 3 Mean (SD) or n (%)	Change score Mean (SD)	Baseline Mean (SD) or n (%)	Time 1 Mean (SD) or n (%)	Change score Mean (SD)	Time 2 Mean (SD) or n (%)	Change score Mean (SD)	Time 3 Mean (SD) or n (%)	Change score Mean (SD)	Time 3
No. of participants	$N = 30$	$N = 28$		$N = 29$		$N = 30$		$N = 30$	$N = 28$		$N = 30$		$N = 28$		
APOS[a,b]	12.0 (4.1)	13.0 (3.8)	1.0 (5.6)	16.0 (2.0)	4.0 (4.6)	14(1.7)	2.0 (4.4)	14.0 (2.9)	11.0 (1.7)	−3.0 (3.4)	9.0(1.2)	−5.0 (3.1)	9.0 (1.5)	−5.0 (3.3)	0.7 [0.17–1.23]
MOSHI[a,c]	30.1 (9.2)	25.5 (13.6)	−4.6 (16.42)	19.5 (12.2)	−10.6 (15.3)	53.2 (7.8)	23.1 (12.1)	28.6 (7.5)	66.4 (6.5)	39.8 (9.9)	74.0 (4.0)	47.4 (8.5)	83.0 (2.9)	56.4 (8.0)	0.7 [0.17–1.23]
PEQ[a]	31.0 (1.9)	32.0 (2.1)	1.0 (2.8)	33.0 (1.2)	2.0 (2.2)	32.0 (1.5)	1.0 (2.4)	30.0 (2.7)	26.0 (1.9)	−4.0 (3.3)	24.0 (2.7)	−6.0 (3.8)	24.0 (2.4)	−4.0 (3.6)	0.8 [0.27–1.31]
CAREM[a]	5.0 (3.3)	3.0 (2.8)	−2.0 (4.3)	5.0 (1.1)	0.0 (3.5)	7.0 (1.6)	2.0 (3.7)	5.0 (3.3)	23.0 (3.1)	18.0 (4.5)	27.0 (2.2)	22.0 (4.0)	33.0 (1.4)	28.0 (3.6)	1.0 [0.45–1.55]
PD[a]	30.0 (5.2)	28.0 (6.5)	−2.0 (8.3)	38.0 (4.5)	8.0 (6.9)	30.0 (3.9)	0.0 (6.5)	26.0 (8.1)	23.0 (6.0)	−3.0 (10.1)	16.0 (3.8)	−8.0 (6.9)	16.0 (3.8)	−10.0 (6.9)	0.7 [0.17–1.23]

[a]Some items were reversed
[b]Lower scores = better outcomes
[c]Higher scores = better outcomes

Table 6. Quotes from PLWH and HCP.

1. "Interestingly the past 3 months have been magical because it looks like all the staff have been replaced with new ones who are more interested in me as a person the care is different and it's more like a partnership between me and the staff now" PTQI PLWH 2.
2. "The way staff assessed my problems step by step wanting to know all about me and my life outside HIV and more importantly my involvement in care and staff planning my care with me was the main thing that helped me most" PTQI PLWH 7.
3. "This enhanced care is like an eye opener for me because it helped me understand the daily challenges our clients go through in terms of spiritual and enormous psychological issues that we don't get to know because we don't ask them" PTQIS HCP 1.
4. "Clients are very happy and excited about being part of the decisions being made about their care. I think that this holistic approach is very promising because of the effect it had on our clients being able to contribute to their care plan" PTQIS HCP 6.
5. "Looking back at the way I used to practice compared to now, I think that this holistic approach is very promising. This is because of the effect it had on our clients, the fulfilment I get being able to partner with my clients and coming up with a care decision that we both agree on and seeing them for this past 3 months more enthusiastic about their care its really satisfying" PTQIS HCP 3.
6. "Now I feel much better because I don't have to keep quiet about my symptoms of pain or any other physical problems because if I don't talk about them staff will keep on asking me about my physical health. So now staff always ask me about pain and other problems which I always discuss them with staff and together we decide what will help me better" PTQI PLWH 9.
7. "My only concern is that the process of care delivery is time consuming and sometimes you get lost in your clients' problems however I feel fulfilled that I am able to assess and manage clients' needs holistically" PTQIS HCP 4.
8. "my experience over the past 3 months has been very good and different because the thought of knowing that there is someone to talk to at the clinic who care to ask about my health and living situations really motivates me to keep coming to the clinic" PTQC PLWH 3

protocol is ultimately feasible; and therefore, concluded that it would be worthwhile to use the protocol tested to guide a definitive trial of the CECI. The CECI is novel, it was purposely developed with PLWH to improve their person-centred outcomes, and these findings are important in driving forward the PCC agenda for PLWH in Africa.

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Appendix DD. Systematic review manuscript for thesis Phase 1

Health Sciences

Are patient outcomes improved by models of community HIV management which aim to be person-centred? A systematic review of the evidence.

Journal:	*AIDS Care - Psychology, Health & Medicine - Vulnerable Children and Youth Studies*
Manuscript ID	Draft
Journal Selection:	AIDS Care
Keywords:	Person-centred care, HIV/AIDS, Holistic care, Holistic assessment, Community-based care

Are patient outcomes improved by models of community HIV management which aim to be person-centred? A systematic review of the evidence.

Are patient outcomes improved by models of community HIV management which aim to be person-centred? A systematic review of the evidence.

Abstract

An estimated 37.9 million people globally were living with HIV in 2018. People living with HIV/AIDS (PLWHA) often experience multidimensional symptoms and concerns which impact on their quality of life (QoL). UNAIDS advocates for person-centred care (PCC) delivery for PLWHA to improve care outcomes and wellbeing. We aimed to appraise the evidence of person-centred models of community HIV management delivered or led by trained healthcare professionals (HCP) and the impact on outcomes for PLWHA. A systematic review was conducted in line with PRISMA guidance. Six electronic databases (CINAHL, Embase, PubMed, Medline, PsycINFO and Web of Science) were searched from January 1980 to April 2019, using pre-defined search terms. We included primary evaluation studies of any design of PCC models; for adults aged ≥15 years with HIV; that are delivered or led by trained HCP; in the community. Data were extracted including study location, design, quality, outcomes measured and effectiveness. 5 out of 1,393 studies met the inclusion criteria, of which, 4 were from a high-income country and 1 from a lower-middle income country. Study designs included pilot and feasibility studies n=3, qualitative observational study n=1 and a randomised controlled trial n=1. 327 PLWHA and 68 HCP participants were included in the 5 studies retained. Of the PCC components (physical, psychological, social and spiritual wellbeing) delivered alongside HIV clinical management, one study delivered 2, two studies delivered 3 and two studies delivered all 4 components. Only one study used validated tools to measure outcomes and reported positive effects on self-reported mental health related QoL and psychosocial wellbeing. This review highlights the lack of outcomes evidence for person-centred HIV care. Clear articulation of the meaning and practice of person-centred HIV care, implementation strategies, and measurement of outcomes are needed to meet policy recommendations.

Keywords: Person-centred care; HIV/AIDS; Holistic care; Holistic assessment; Community-based care.

Background

In 2018 an estimated 37.9 million people globally were living with HIV, with approximately 23.3 million accessing antiretroviral therapy (ART), 1.7 million people were newly infected and 770, 000 people died from AIDS-related disease (UNAIDS, 2019). With respect to the UNAIDS 90-90-90

treatment targets set for the end of 2020 (WHO, 2016b), 79% of people living with HIV knew their status; 78% of people who knew their status were accessing treatment; and 86% of people accessing treatment were virally suppressed (UNAIDS, 2019).

A critical action to achieve the 90-90-90 targets is to deliver 'person-centred and holistic care' (WHO, 2016b). Mezzich defined person-centred care (PCC) as care 'dedicated to the promotion of health as a state of physical, mental, sociocultural, and spiritual well-being, as well as to the reduction of disease, and founded on mutual respect for the dignity and responsibility of each individual person'(Mezzich, 2012). Selman et al. noted the importance of holistic assessment to achieve this, noting that spiritual wellbeing receives less attention in person-centred approaches (Selman et al., 2013). Holistic care is described as recognising a person as a whole and acknowledging the interdependence of one's physical, psychological, social, and spiritual attributes, in disease management and prevention (Huljev & Pandak, 2016; Zamanzadeh et al., 2015).

Person-centeredness is potentially beneficial to: (1) individuals and their families (care addressing what matters to the individual, shared-decision making and collaborative care planning); (2) care providers (improved job satisfaction, opportunities for education and training to learn new skills, including team working); (3) communities (improved access to care and health outcomes, including greater levels of health-seeking behaviour); and (4) health systems (enables better allocation of scarce resources and reduces unnecessary use of health facilities) (WHO, 2019).

UNAIDS emphasises the vital role of community service delivery and sets a target of increased access to care by delivering 30% of HIV care in community settings (UNAIDS, 2014). Community services have played significant roles as part of a comprehensive HIV response of many nations (Rodriguez-García et al., 2013). Two groups provide CBHS: formally trained healthcare professionals (nurses, public health inspectors, health visitors, doctors etc.), and community health workers (volunteers, peers etc.) (WHO, 2016a).

Owing to UNAIDS advocacy for person-centred holistic care and care delivered in community settings to achieve the 90-90-90 targets, care services urgently require evidence of PCC models to optimise outcomes for PLWHA. Additionally, to date, no review has considered the breadth of

person-centred outcomes considered relevant to PLWHA. This review aims to identify and appraise the evidence for person-centred models of community HIV management delivered or led by healthcare professionals (HCP), and to assess their impact on outcomes for PLWHA.

Methods

Review question

Are patient outcomes improved by models of community HIV management which aim to be person-centred?

Design

A systematic review was conducted in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009).

Review objectives

(1) To describe the structures, components and processes of person-centred HIV care delivered in community settings using the Donabedian framework of quality healthcare (Donabedian, 1988)

(2) To appraise effectiveness in terms of patient outcomes

(3) To evaluate the quality of the evidence.

Defining models of person-centred care and community-based health services

This review considered models of care that are described within the peer-reviewed literature as person-centred and address person-centred outcome domains including physical, psychological, social and spiritual wellbeing alongside HIV disease management (Huljev & Pandak, 2016; Mezzich, 2012; Selman et al., 2013; Zamanzadeh et al., 2015).

Community-based health services (CBHS) as defined by WHO, include outreach services, primary or community or mobile clinics, home visit and home-based care services either delivered or led by formally trained HCP (WHO, 2016a). The rationale for choosing only those services delivered or led by HCP is that, trained professionals are required to assess, plan and manage HIV care including

giving appropriate medications, referrals, and delivering person-centred care as part of disease management.

Search strategy

Relevant studies were identified by searching electronic databases: CINAHL, Embase, PubMed, Medline, PsycINFO and Web of Science, and searching reference lists of included studies to identify additional studies. Studies from 1980 (HIV was first discovered in the 1980s) to April 2019 and updated in January 2020 were included.

The search strategy combined the keywords i) 'HIV' OR 'AIDS' AND ii) 'person-centred care' OR 'patient centred care' OR 'client-centred care' OR 'family-centred care' OR 'personalised care' OR 'individualised care' OR 'holistic care' AND iii) 'community care' OR 'community healthcare' OR 'primary care' OR 'primary health care' OR 'home-based care' OR 'community and home-based care' AND iv) 'interventions' OR 'implementation' OR 'evaluation' OR 'effectiveness'. Multiple keywords were used to broaden the search and increase sensitivity to the databases.

Inclusion and exclusion criteria

Inclusion and exclusion criteria are presented in Table 1. Primary studies of any design that reported on community HIV management described as person-centred delivered or led by HCP were included.

[Insert Table 1]

Data collection and extraction

The first reviewer (MA-O) imported all search results to Endnote reference manager version X9, de-duplicated, then screened titles and abstracts of all identified studies. Retained studies were screened against inclusion/ exclusion criteria, any article for which inclusion was unclear were discussed with a second reviewer (KB) and if necessary adjudicated by a third reviewer (RH). Full texts of the articles were obtained if abstracts did not contain sufficient information to determine the relevance of an article. We extracted studies that used the term 'person-centred', including alternative spelling or

synonyms (see search terms). Studies not meeting the inclusion criteria were excluded from the analysis.

Analysis

Summary statistics were used to report the number of published studies and presented in a PRISMA flow diagram in figure 1. Data were extracted and analysed using the Donabedian framework of quality (Donabedian, 1988). These variables were extracted to a common table (see Table 2), including aims/objectives, design and sample size, care structure, processes, person-centred and clinical components delivered, outcomes and measures used, including results and effectiveness. We analysed descriptions of PCC models, their domains and findings from the studies, and mapped them onto Mezzich's PCC domains as presented in Table 3. Instruments used to measure PCC were extracted including any validated measures and other means of assessing effectiveness of PCC delivered. Countries where studies were conducted were classified by GDP per capita using World Bank classification system (World Bank, 2019). Both qualitative and quantitative studies were analysed descriptively, and then findings integrated. All studies addressing any domain of PCC model were retained in the final analysis.

Study quality was evaluated using the Standard Quality Criteria for Evaluating Primary Research papers (Kmet et al., 2004).

Results

Study characteristics

The search retrieved 1,720 papers and hand searching yielded 9 additional papers as shown in the PRISMA flow diagram in Figure 1 (Moher et al., 2009). Of the 1,393 papers screened, 1,352 were excluded, leaving 41 papers for full-text review. Of these, 36 papers were excluded as they did not meet the inclusion criteria (reasons reported in Figure 1). Five papers were retained for final analysis. A total of 327 PLWHA and 68 HCP participants were included in the five studies retained. Three studies were classified as pilot and feasibility study (Bendetson et al., 2017; Morgan, 2014; Robinson

et al., 2006); one qualitative observational study (Steward et al., 2018); and one randomised controlled trial (RCT) (Lowther et al., 2015).

[Insert Figure 1]

Of the five studies retained, n=4 papers (80%) reported data from USA, a high-income country and n=1 paper (20%) reported data from Kenya, a lower-middle income country in line with World Bank classifications (World Bank, 2020) (see Table 2). The median and range of the study design quality score of all retained studies are 0.7 and 0.6 – 0.9 respectively.

[Insert Table 2]

Person-centred care models

Components of care delivered were categorised according to Mezzich's definition (promotion of physical, mental, sociocultural, and spiritual well-being, alongside the reduction of disease Mezzich, 2012), see Table 3. Of the five studies retained, n=1 delivered two components, n=2 three components and n=2 delivered all four components.

[Insert Table 3]

As demonstrated in Table 3, although all these studies claimed to deliver PCC, only two studies delivered all domains defined by Mezzich (Mezzich, 2012). All five studies delivered care that addressed physical and psychological wellbeing, and 4 studies added social care, confirming previous reports that less attention has been given to spiritual wellbeing (Selman et al., 2013).

PCC components delivered

(i) Physical wellbeing

All five (100%) studies delivered PCC domains that focused on physical wellbeing of PLWHA (see Table 3). These include medical treatment, selfcare, nutrition, pain other symptoms management (Bendetson et al., 2017; Lowther et al., 2015; Morgan, 2014; Robinson et al., 2006; Steward et al., 2018) and using tools like yoga, meditation and Reiki practice (Reiki is a Japanese technique for relaxing and reducing stress).

(ii) Psychological wellbeing

All five (100%) studies retained provided psychological care in addition to the physical care for PLWHA. The main forms of psychological care provided include counselling delivered through motivational interviewing, relationship building, and yoga, meditation and Reiki, as described above (Bendetson et al., 2017; Lowther et al., 2015; Morgan, 2014; Robinson et al., 2006; Steward et al., 2018).

(iii) Social wellbeing

Four (80%) of the studies retained provided social care in addition to physical and psychological care to PLWHA (Bendetson et al., 2017; Lowther et al., 2015; Morgan, 2014). Social care provided included support for developing meaningful relationships, with stigma and discrimination leading to social isolation and burden of disclosure, legal issues, transportation, housing, the burden of caregiver and breadwinner roles as well as childcare issues.

(iv) Spiritual wellbeing

Two (40%) of the five studies retained included spiritual assessment (Lowther et al., 2015) and provided spiritual support (Lowther et al., 2015; Morgan, 2014) for PLWHA in addition to physical, psychological and social care. This spiritual care included supporting PLWHA to identify a reason, to feel at peace, and to renew relationships with faith or other supernatural being considered important to them through meditation and Reiki Healing Circles.

Using the Donabedian framework

This review used the Donabedian framework structure, process and outcome components (Donabedian, 1988), to assess the quality of care delivered in the retained studies.

Care structure

Structure represented the physical setting where care was delivered including HCP who delivered the care. Three studies utilised outpatient services within primary and community clinics (Bendetson et al., 2017; Lowther et al., 2015; Steward et al., 2018), and the remaining two studies delivered services in a home-based and residential facility (where PLWHA lived permanently) (Morgan, 2014; Robinson et al., 2006). Services provided for PLWHA within these care structures were delivered or led by trained HCP.

Care process

Process comprised the approaches used to deliver care, which was dependent on the care structures or mechanism and resources required to deliver care, bringing about result that impacted on patient outcomes. Care processes described by all studies included consultations, yoga, meditation and Reiki practice for medical treatment, adherence, selfcare, nutrition, fatigue, muscle aches, weakness, pain other symptoms assessment and management, (physical); counselling delivered through motivational interviewing, relationship building, and yoga, meditation and Reiki practice for depression, perceived stress and psychological distress (psychological) (Bendetson et al., 2017; Lowther et al., 2015; Morgan, 2014; Robinson et al., 2006; Steward et al., 2018).

Those who provided social care also utilised client-centred communication and Reiki practice to develop meaningful relationships and provision of material support to mitigate against stigma and discrimination, social isolation, burden of disclosure, legal issues, transportation, housing, the burden of caregiving and breadwinner roles (Lowther et al., 2015; Morgan, 2014; Robinson et al., 2006). Moreover, those who provided spiritual care supported PLWHA through meditation and Reiki practice to identify a reason to feel at peace, and to renew relationships with faith or other supernatural being considered important to them (Lowther et al., 2015; Morgan, 2014).

Authors also described linkage to care specialist (LTC-S), which is a HCP with experience in crisis counselling, who uses a client-centered approach to draw on motivational interviews and strength-based case management techniques to address negative emotions (fear and stigma) surrounding new HIV diagnosis (Bendetson et al., 2017). HCP were also trained to use a standardised multidimensional assessment and care planning instrument developed from existing assessment schedules from palliative care (PC) services across Africa, and systematically assessed and addressed physical, psychological, social, and spiritual wellbeing, among PLWHA (Lowther et al., 2015).

Additionally, practical holistic self-care tools including Yoga, JourneyDance, Meditation (a state of heightened mental awareness and inner peace), Reiki Healing Circles and Reflective Journaling (a guided questioning and restructuring strategies) were utilised in managing symptoms and concerns of PLWHA in the domains of psychological, physical, social and spiritual wellbeing (Morgan, 2014). A palliative care approach was also used to identify and manage physical and psychosocial symptoms among PLWHA (Robinson et al., 2006). Furthermore, HCP promoted patient activation including expanded clinic hours, same day appointments, patient electronic health record portals to collaboratively develop and implement care plans (Steward et al., 2018).

Outcomes

Various outcomes were described including linkage to care, adherence, retention in care, viral suppression, and improvement in physical, psychological, social and spiritual wellbeing. Of these outcomes only one study used validated measures to measure care outcomes (Lowther et al., 2015). The most common outcomes assessed in these studies were adherence, retention in care, viral suppression, linkage to care and improvement in physical and psychological wellbeing (Bendetson et al., 2017; Lowther et al., 2015; Morgan, 2014; Robinson et al., 2006; Steward et al., 2018). The least outcomes assessed were social (Lowther et al., 2015; Morgan, 2014; Robinson et al., 2006) and spiritual wellbeing (Lowther et al., 2015; Morgan, 2014).

The client-centred linkage intervention process used was effective in linking n=111 (94%) newly diagnosed PLWHA to care within an average of 25.5 days and retained 91.9% of the sample linked. Linkage to care was described as a face-to-face visit with an HIV medical provider within 3 months of diagnosis; and retention in care described as two HIV medical visits at least 3 months apart within a 12-month period (Bendetson et al., 2017).

The HCP trained to use standardised multidimensional assessment and care planning (Lowther et al., 2015), resulted in multidimensional outcomes measured with validated tools as follows: pain measured with APCA POS comparing a PCC intervention to standard care found no significant effect on pain (coefficient -0.01, 95% CI -0.36 to 0.34, p=0.95); physical health measured with MOS-HIV had no significant effect on physical health (coefficient 0.44, 95% CI 0.02 to 0.91, p=0.06) but was effective on mental health (coefficient 0.61, 95% CI 0.13 to 1.10, p=0.01). Furthermore, psychological morbidity measured with GHQ-12 was effective (coefficient -0.50, 95% CI -0.97 to -0.03, p=0.04). Also, concerns such as APOS worry (coefficient -0.37, 95% CI -0.09 to 0.83, p=0.11); ability to share feelings (coefficient 0.93, 95% CI 0.28 to 1.57, p=0.005); feeling life worthwhile (coefficient 0.23 95% CI -0.48 to 0.94, p=0.52); feeling at peace (coefficient 0.37 95% CI -0.18 to 0.93, p=0.19); help and advice for family to plan for the future (coefficient 0.78 95% CI 0.28 to 1.28, p=0.002) were all significantly effective on the wellbeing of PLWHA (Lowther et al., 2015).

The use of practical holistic self-care tools including Yoga, JourneyDance, Meditation, Reiki Healing Circles and Reflective Journaling was reported to be effective in improving mood, perceived stress, quality of life in addition to promoting physical, emotional, mental, and spiritual healing in PLWHA (Morgan, 2014). Also, the palliative care approach used reported improvement in physical, psychological and social wellbeing (Robinson et al., 2006). Finally, patient activation process used, especially attributes on open communication was effective in improving stigma and clinic utilisation, as PLWHA were able to talk to their providers through email, phone calls or in person without holding back any information (Steward et al., 2018).

Discussion

This review synthesised the data for PCC models of care delivered in HIV management services that aimed to deliver PCC in community settings. Five studies were retained of which, 4 were from a high-income country and 1 from a lower-middle income country; and a total of 327 PLWHA and 68 HCP participants were included in these studies. Of the PCC components (physical, psychological, social and spiritual wellbeing) delivered alongside HIV clinical management, one study delivered 2, two studies delivered 3 and two studies delivered all 4 components. Only one out of these five studies used validated tools to measure outcomes.

The delivery of these PCC components with HIV disease management is crucial given the distressing symptoms and concerns experienced by PLWHA (Harding et al., 2010; Harding, Selman, et al., 2012; Harding et al., 2013), which impact on their wellbeing and quality of life (Harding et al., 2012; Harding et al., 2014). Greater attention has been paid to HIV clinical management at the expense of broader psychological, social and spiritual concerns that persist despite treatment advances (Fontaine et al., 1999; Harding et al., 2010). This review demonstrates that still this is the case consequently, services provided to PLWHA should consider delivering PCC alongside HIV clinical management in order to manage their symptoms and concerns holistically.

Care structures where PCC components were delivered included community settings such as primary care, home-based care and a combination of residential and outpatient services, where care was delivered or led by trained HCP. Expanding community-based approaches for HIV disease management is vital to the long-term success of the AIDS response as it improves access to treatment and the quality of care outcomes for PLWHA (UNAIDS, 2015). Consequently, UNAIDS has launched Fast-Track actions towards ending the AIDS epidemic by 2030 with an expectation of increasing the percentage of community-based services from 5% to 30% (UNAIDS, 2014). While we recognise there are all kinds of exciting models of lay community-based services including The Friendship Bench project (Chibanda et al., 2016); and use of adherence counsellors (Abas et al., 2018), if these lay workers cannot carry out clinical

management of patients' symptoms and concerns they may not be able to manage their needs holistically.

Care processes such as open communication, counselling, relationship building, training HCP to use holistic assessment tool with care planning in addition to training PLWHA to use practical self-care tools including Yoga, JourneyDance, meditation, Reiki Healing Circles and Reflective Journaling to improve their health and wellbeing were used across the studies reviewed. It has been argued that a good quality care must focus on the person and not their disease only in ensuring that care delivered to PLWHA is person-centred (British HIV Association, 2018). PCC focuses on the person as a unique individual in considering their problems, symptoms and concerns in order to respond to their needs and preferences in humane and holistic ways, in addition to training HCP who respond to the needs of patients and making these patients participants in their care (Moore et al., 2017; Sidani, 2008).

Moreover, PCC care has been perceived as a Western-originated concept that is potentially applicable universally, despite it not being tested in African context (De Man et al., 2016; Setlhare et al., 2014). It has also been argued that PCC is context specific (Gabrielsson et al., 2015), implying that although PLWHA experience symptom burden across the domains of physical, psychological, social and spiritual wellbeing, the specific needs within these domains require contextual exploration. Therefore, it is critical to understand the contextual meaning of these domains as applied to the symptom burden of PLWHA in order to develop PCC interventions that address specific needs and are socio-culturally appropriate in improving care outcomes. For example a study explored what constitutes PCC for PLWHA in the context of Ghana and found that PLWHA understand PCC as care that involves them in their care decisions, which is concerned about the whole person and not only viral suppression and addresses what matters to them (Abboah-Offei et al., 2019).

The implementation of PCC by Lowther et al. improved psychosocial wellbeing and self-reported mental health related quality of life for PLWHA (Lowther et al., 2015). Similar PCC

interventions could help to improve outcomes for PLWHA and to achieve global targets such as the 90-90-90 targets.

Limitations

The limitations of this review include the inclusion of only studies published in English resulting in publication bias. Furthermore, studies included had to say they were delivering PCC (albeit using a broad range of possible synonyms), implying that there is a possibility some studies may have delivered care in line with PCC but because they did not explicitly state it, those studies were excluded. Also, this review has a broad understanding of PCC which is Western in origin, and therefore cannot be generalised.

Clinical and research implications

Leaving these PCC domains (physical, psychological, social and spiritual wellbeing) unaddressed may have major clinical implications including increased infectiousness, viral resistance and potential treatment failure (Gonzalez et al., 2011; Nachega et al., 2013). Therefore, future research should seek to explore the meaning and practice of person-centred HIV care contextually, and to develop PCC interventions that address specific contextual needs, in addition to selecting appropriate validated outcome measures to measure the domains of need addressed by these interventions.

Conclusion

This review highlights the lack of research evidence in terms of PCC components (physical, psychological, social and spiritual wellbeing) delivered alongside HIV clinical management in community settings. Findings also indicate that PCC interventions that focus on training HCP to holistically assess and manage clinical symptoms and concerns of PLWHA as part of the care delivery process, can improve outcomes including wellbeing and quality of life for PLWHA. Consequently, future plans for PCC intervention development should focus on training HCP to identify and manage multidimensional needs of PLWHA, as well as explore context specific

PCC components for PLWHA in informing future PCC interventions and policy recommendations that can translate into clinical practice.

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This study was conceived and designed by ---------- and ----------. The first reviewer ---------- imported all search results to Endnote reference manager version X9, de-duplicated, then screened titles and abstracts of all identified studies. Retained studies were screened against inclusion/ exclusion criteria, any article for which inclusion was unclear were discussed with a second reviewer ------- and if necessary adjudicated by a third reviewer ---------. All authors critically appraised and contributed to the manuscript.

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Table 1. Inclusion and exclusion criteria

Inclusion criteria	*Exclusion criteria*
• Primary studies of any designs reporting models of person-centred care for PLWHA led by formally trained HCP and delivered in the community • Studies of adults aged 15 years and above (UNAIDS, 2015b). • Studies published from 1980 to date.	• All studies of any design reporting on HIV testing/ counselling/ adherence only would be excluded. • Studies reporting on CBHS for children and adolescents (from age 0-14 years) • Any CBHS neither delivered by nor/ supervised by professionals will be excluded. • Editorials, opinion pieces, conference abstracts, descriptive studies, case studies and reviews. • Studies presenting adjunct services only, without management of HIV disease.

Table 2: Data extraction table

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
Bendetson et al., 2017, USA, High-income.	0.7	To evaluate the linkage to care specialist (LTC-S) intervention among those who were newly diagnosed of HIV in order to assess early emotional and cognitive reactions following a new HIV diagnosis, and their potential impact on linkage to care (LTC). Single group non-trial feasibility cross-sectional study, N=118.	Outpatient (participants were considered linked to care if they attended a medical visit with any HIV primary care provider within 3 months of diagnosis)	**Client-centred Linkage Intervention** *Phase 1*: mainly consists of client-centred, resiliency-based counselling and support, which starts immediately after a positive HIV test result with the aim of establishing a support and linkage plan. *Phase 2*: attempts to promote a sense of a responsive care system by demonstrating the flexibility and availability of the LTC-S through frequent meetings, phone calls text messages and/or email as individual needs dictates. LTC-S also focuses on helping clients develop or reinforce the concrete skills (planning ahead, making/ rescheduling appointments) that are required for successful engagement in care. *Phase 3*: is shaped mainly by client's readiness to engage in care, reflecting an efficient use of LTC-S and care team resources. For individuals who do not link initially but demonstrate interest in	i. Psychological care (counselling and support). ii. Physical care (addressing self-care goals and entering HIV medical care).	*Primary outcome:* Linkage to care, treated as a dichotomous (Yes/No) variable (Linkage to care is a face-to-face visit with an HIV medical provider within 3 months of diagnosis) *Secondary outcome:* Retention in care and viral suppression at retention, both treated as dichotomous (Yes/No) variables (Retention in care is defined as 2 HIV medical visits at least 3 months apart within a 12-month period. Viral suppression is having a viral load <200 copies per millilitre). No validated measure was used.	*Primary outcome:* Of the 118 recruited, 111 (94%) took an average of 25.5 days to link to care (range: 1-72days); the LTC-S spent an average of 2.1hours working with each participant (range: 0.5-5.2 hours). Interactions were mainly in-person meetings (mean: 1.8 per person) and phone conversation (mean: 2.7 per person). *Secondary outcome:* 102 participants (91.9%) of those linked were retained in care for the year following linkage. The development of individualised linkage and support plans through LTC-S encouraged autonomous and promoted a sense of personal control over self-care decisions. This client-centred, strength-based intervention was successful in linking 94% of enrolled participants in care. Results demonstrate that client-centred, resiliency-based LTC

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
				receiving care at the Center, the LTC-S introduces clients to care team members to help establish relationships. If any appointments are missed, the LTC-S intensified outreach to explore challenges and identify specific barriers to care. The LTC-S strategises with clients, providing referrals to any resources they may view as more pressing than HIV care at the time, and reschedules appointments when appropriate.			services can be seamlessly integrated into an existing HIV testing program, thereby increasing the chances that newly diagnosed individuals will link to care.
Lowther et al., 2015b, Kenya, Lower-middle income.	0.9	To test the effectiveness of integrating palliative care into existing outpatient care for PLWHA on ART; RCT, longitudinal study N=120	Outpatient care in a community hospital	**Holistic patient-centred care** This intervention was delivered by two experienced nurses who received 2 weeks of fulltime palliative care (PC) training delivered by Kenyan experts from the Kenyan Hospice and Palliative Care Association (KHPCA). The experts used KHPCA's standard PC training programme with additional focus on HIV PC and quality of life in chronic disease. The training was didactic and delivered by nurses, doctors, and counsellors, with 4 days of shadowing a PC clinician, who became their clinical mentor after the training.	i. Physical (pain and symptom management, with nutrition services). ii. Psychological (not described), iii. Social (providing ethical and legal support and others not described) iv. Spiritual wellbeing (supporting PLWHA to	*Primary outcome*: 1-point change in pain score measured with APCA POS. *Secondary outcome*: i. 10-point change in quality of life (QoL) score (physical and psychological dimensions) measured with the MOS-HIV; ii. Psychological morbidity measured with General Household Questionnaire-12 (GHQ-12);	*Primary outcome:* i. Pain - Control: [1.0 (IQR 0.0-2.0) at baseline to 5.0 (3.0-5.0)] at final timepoint; Intervention: [1.0 (0.0-2.0) at baseline to 4.5 (3.0-5.0) at final timepoint]. Compared to standard care, the intervention had no significant effect on pain (coefficient -0.01, 95% CI -0.36 to 0.34, p=0.95). *Secondary outcome:* i. MOS-HIV QoL - Physical health (coefficient 0.44, 95% CI 0.02 to 0.91, p=0.06); Mental health (coefficient 0.61, 95% CI 0.13 to 1.10, p=0.01). ii.GHQ-12 Psychological morbidity (coefficient -0.50, 95%

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
				Topics included pain management, symptom management, nutrition, psychosocial and spiritual assessment and care, breaking bad news, ethical and legal issues, and bereavement. The nurses used a standardised multidimensional assessment and care planning instrument for all PLWHA allocated to the intervention to provide holistic PCC. The instrument was developed from existing assessment schedules from PC services across the region and systematically addressed physical, psychological, social, and spiritual wellbeing and patients' understanding of their illness and adherence to ART. Care plans were included to plan and review care against prioritised needs. The nurses had a weekly clinical support with their clinical PC mentor to review complex cases.	understand the meaning of their illness and to find peace)	iii. Palliative care-related problems and concerns measured with APCA POS and ART adherence measured by asking questions about missed doses of ART and weather the timing was appropriate. Apart from ART adherence assessment, all measures used are validated.	CI -0.97 to -0.03, p=0.04). iii. APCA POS (Palliative care related problems and concerns) total (0.69, 95% CI 0.26 TO 1.12, p=0.002): Symptoms (coefficient -0.05, 95% CI -0.39 to -0.29, p=0.78); Worry (coefficient -0.37, 95% CI -0.09 to 0.83, p=0.11); Ability to share feelings (coefficient 0.93, 95% CI 0.28 to 1.57, p=0.005); Feeling life worthwhile (coefficient 0.23 95% CI -0.48 to 0.94,p=0.52); Feeling at peace (coefficient 0.37 95% CI -0.18 to 0.93, p=0.19); Help & advise for family to plan for the future (coefficient 0.78 95% CI 0.28 to 1.28, p=0.002). Person-centred assessment and care delivered by trained nurses had positive effect on self-reported mental health related QoL and psychosocial wellbeing.
Morgan, 2014, USA, High-income.	0.7	To examine the feasibility of an ongoing holistic wellness program in a residential facility for PLWH, Single group non-trial	HIV/AIDS community service organisation providing medical respite, HIV	**Practical holistic self-care tools** used to manage symptoms: i. Use of yoga and JourneyDance to improve mood, perceived stress, and quality of life;	i. Physical (JourneyDance, Meditation, Reiki Healing Touch) ii. Psychological	Physical, psychological, social and spiritual wellbeing Improvement in physical, psychological, social	i. All 10 participants either maintained or progressed to the next behavioural health treatment level and no reported drug or alcohol relapse was noted during the 4-week program. ii. Survey responses from

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
		feasibility cross-sectional study, N=10.	case management, HIV testing and counselling, impatient chemical dependency treatment, mental health therapy, support groups, assisted living and independent housing	ii. Use of meditation (a state of heightened mental awareness and inner peace) to promote mental, physical, and spiritual benefits; iii. Use of Reiki Healing Circles (a Japanese practice for relaxation) to reduce stress and may also promote physical, emotional, mental, and spiritual healing; iv. Use of Reflective Journaling (a guided questioning and restructuring strategies) to help PLWHA to examine their feelings and cognitions surrounding maladaptive health behaviours through interactive journaling binders.	(Yoga, JourneyDance, Meditation, Reflective Journaling) iii. Social (Reflective Journaling and JourneyDance), iv. Spiritual wellbeing (Meditation, Reiki Healing Touch)	and spiritual wellbeing. No validated measure was used	PLWHA consistently indicated a feeling of calm with more energy, physically stronger, sleeping better, more physically stable, and generally better equipped to selfcare. iii. PLWHA also expressed a feeling of patience, increased mental focus, and confidence in their ability to address everyday issues and the physical symptoms associated with HIV. iv. 3 of the 10 reflective journals were 100% completed. Others reported still working on their journals and intended to complete all the guided questions. All 10 PLWH agreed that the journal should be incorporated into future programs. v. 9 of the 10 PLWHA completed the Reiki Healing Circles practitioner training and received Level 1 practitioner certification. vi. 5 weeks post-program meeting held revealed three main themes: a) PLWHA want the holistic wellness program to be mandatory; b) PLWHA felt

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
							empowered to have acquired more tools to practically integrate into their lives and c) PLWHA requested that the holistic activities become part of an ongoing outpatient activity.
Robinson et al., 2006, USA, High-income.	0.6	To describe nursing interventions provided to PLWHA in a home setting using palliative care framework, Single group pilot study using a cross-sectional design, Nurses n=8, PLWH n=26.	Home-based care	Care delivery with **palliative care** philosophy i. Nurses were instructed to audiotape a description of the intervention they provided in home visits right after he visit; ii. The principal investigator conducted an observation home visit, wrote and discussed every intervention observed with the nurse after each visit; iii. Sign and Symptom Checklist was used to determine whether PLWH were experiencing HIV-related symptoms "today" and if so, to rate the symptoms as mild, moderate or severe.	i. Physical (symptom assessment and management) ii. Psychological (allowing PLWHA to talk about their mood and missing their loved ones, ad about their declining health) iii. Social wellbeing (mitigating social isolation of being homebound)	*Outcomes:* i. Symptoms of PLWHA (physical and psychological) measured with Sign and Symptom Checklist for HIV (SSC-HIVrev); ii. Psychological (support was provided to PLWH regarding final arrangements towards the end of life); iii. Social/ emotional concerns (social isolation of being homebound which affected eating habit was addressed by buying client takeaway; and planning a marriage/ vacation trip. Although marriage	i. Top ten symptoms reported by PLWHA were: (a) numbness/ tingling of feet and toes (69.3%); (b) Muscle aches (61.5%); (c) Weakness (61.5%); (d) numbness and Tingling of legs (61.5%); (e) Fatigue (53.9%); (f) Painful joints (57.7%); (g) Thirst (53.8%); (h) Depression (50%); (i) Shortness of breath with activity (50%); and (j) difficulty concentrating (46.2%). ii. Improvement in psychological and social wellbeing were addressed using a qualitative approach

Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
						did not happen, client still had a vacation with partner). SSC-HIVrev is validated	
Steward et al., 2018, USA, High-income.	0.7	To examine provider and patient perspectives of the patient-centred medical home (PCMH) at five demonstration project sites to understand why the sites emphasise the implementation of PCMH components that did not require patient activation; Qualitative observational study, Providers n=60, PLWH n=53.	Outpatient primary care clinic	**Patient-centred** medical homes HCP relied on patient activation including expanded clinic hours, same day appointments, patient electronic health record portals to collaboratively develop and implement care plans	i. Physical (integrating medical and nonmedical case management) ii. Psychological (not described).	N/A	N=60 key informants and 53 PLWHA were interviewed. i. Both PLWHA and key informants spoke highly of patient-centred medical home's care coordination (new position) component, making it the endorsed mechanism of action; ii. PLWHA also spoke highly of team-based model of care making them able to see any of the team members without any hesitation; iii. PLWHA further reported their clinic utilisation was linked to patient-centred medical home's attributes on open communication as they were able to talk to their providers without holding back any information through email, phone calls or in person. iv. Key informants also spoke highly of PLWHAs' perspectives on patient-centred medical

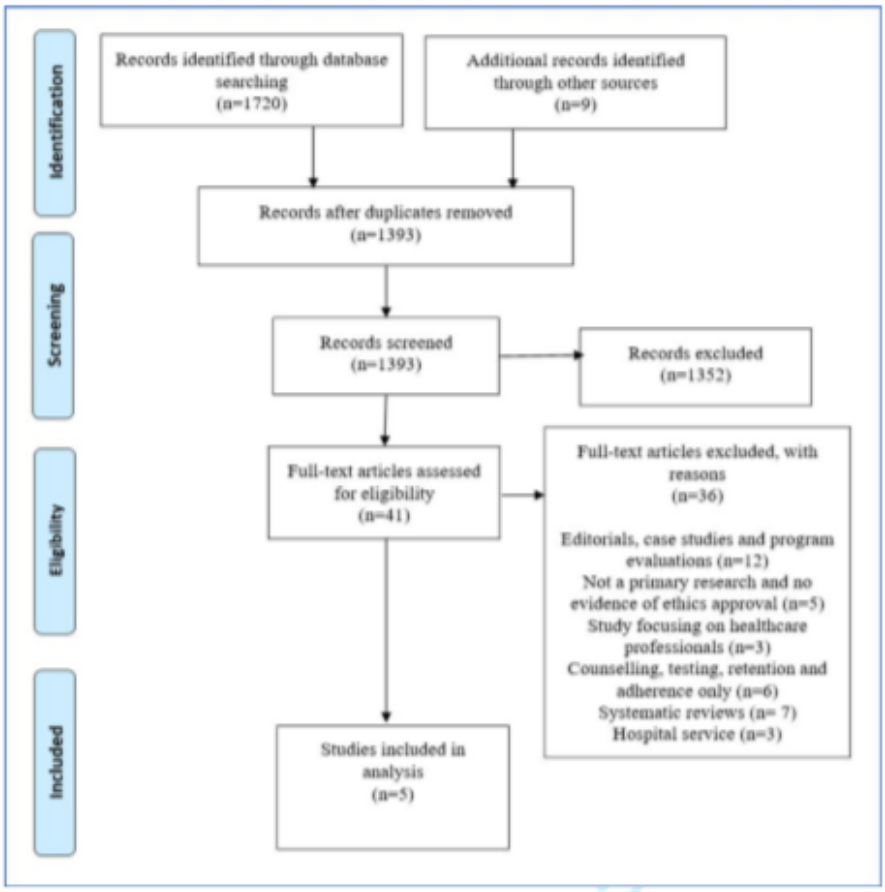
Author/ Year/ Country/ Income status	*Quality Score*	*Study aim/ Design/ sample size*	*Care structure*	*Care processes*	*Person-centred care components*	*Outcomes/ measures used*	*Results and effectiveness*
							home's impact on stigma and how it has elicited a need for creating trusting environments for PLWHA. v. Both key informants and PLWHA emphasised that trust was crucial in overcoming non-attendance to HIV clinics.

Table 3: PCC components delivered in studies retained (n=5) as mapped onto Mezzich domains

Table

Study	Physical	Psychological	Social	Spiritual
(J. Bendetson et al., 2017)	✓	✓	✓	
(K. Lowther et al., 2015b)	✓	✓	✓	✓
(Morgan, 2014)	✓	✓	✓	✓
(L. Robinson et al., 2006)	✓	✓	✓	
(Steward et al., 2018)	✓	✓		

Figure 1: PRISMA flow diagram



Appendix EE. Gnatt chart showing PhD key milestones

The Gantt Chart below show the key milestones of this PhD